

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
1 April 2004 (01.04.2004)

PCT

(10) International Publication Number
WO 2004/026153 A1

(51) International Patent Classification⁷: **A61B 17/34**,
17/02

(21) International Application Number:
PCT/IE2003/000126

(22) International Filing Date:
19 September 2003 (19.09.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
20020754 19 September 2002 (19.09.2002) IE
60/490,909 30 July 2003 (30.07.2003) US

(71) Applicant (for all designated States except US): **ATRO-
POS LIMITED** [IE/IE]; Unit 4, Sunnybank Centre, Bray,
County Wicklow (IE).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **BUTLER, John**

[IE/IE]; 52 Saint Fintan's Park, Deansgrange, Blackrock,
County Dublin (IE). **VAUGH, Trevor** [IE/IE]; Garbally,
Birr, County Offaly (IE). **BONADIO, Frank** [US/IE]; 2
Martello Terrace, Bray, County Wicklow (IE).

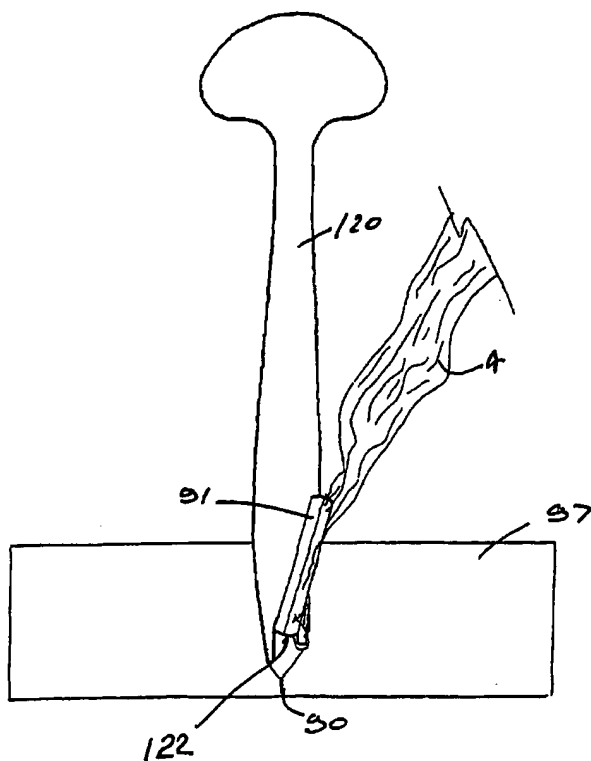
(74) Agents: **O'BRIEN, John, A.** et al.; John A O'Brien &
Associates, Third floor, Duncairn House, 14 Carysfort Ave-
nue, Blackrock, County Dublin (IE).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE,
GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR,
KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK,
MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT,
RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR,
TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

[Continued on next page]

(54) Title: A WOUND RETRACTOR SYSTEM



(57) Abstract: A wound retractor system
comprises a retractor having a distal ring 91 and
a retracting sleeve 4 extending from the ring. An
insertion tool 120 has a distal groove 122 to hold
the ring for insertion of the ring through a small
incision 90 in the abdominal wall 97. The retractor
may be used for retracting an incision to receive
an instrument therethrough. A seal or valve may
be mounted to the retractor through which an
instrument can pass.

WO 2004/026153 A1



European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

— *with international search report*

"A Wound Retractor System"

5 Introduction

This invention relates to a wound retractor suitable for retracting the sides of wound opening laterally.

10 Conventional practice in keyhole or Laparoscopic Surgery uses a trocar to allow the insertion of an instrument into a body cavity such as the abdomen for carrying out a procedure. In carrying out such procedures it is known to insufflate the abdomen to create a working space between the anterior abdominal wall and the viscera. There are a number of problems with the use of conventional trocars. One of the problems
15 with the use of conventional instrument insertion systems is that there is a risk of loss of gas pressure through the margins of the incision. The problem is even more pronounced if an initial incision is made before a first trocar is introduced. Another problem is that typical trocars will extend at least 50 mm into the abdominal cavity taking up precious space. Still another limitation of the conventional trocar is the
20 fact that these long narrow fixed diameter rigid tubes limit both the type of instrument one can use through them, as well as restricting the manoeuvrability of the instrument.

This invention is directed towards providing a retractor system and method which
25 will address at least some of these issues.

Statements of Invention

According to the invention there is provided a wound retractor system comprising:-

5 a retractor having a retracting member for insertion into a wound opening; and

 an insertion tool for inserting or assisting the insertion of or
10 deployment of the retracting member in a wound opening.

10 In one embodiment the insertion tool has a receiver for mounting the retractor to the insertion device.

 The retractor may comprise a distal portion and the receiver is adapted for mounting
15 the distal portion to the insertion tool. The receiver may comprise a groove for receiving the distal portion of the retractor. In one embodiment the distal portion comprises a distal ring member mounted to the retracting member. The distal ring member may be of flexible material. The ring member may be of elastomeric material.

20 In one embodiment the insertion tool comprises an elongate member having a distal end. The distal end of the insertion tool may have a cutting blade for forming an incision.

25 In one embodiment the retractor comprises a proximal ring member and the insertion tool has a pusher to push the proximal member towards a distal member to shorten the axial extent between the proximal and distal ring members. The pusher may comprise a blade.

30

The insertion tool comprises a stop for limiting the extent to which the tool may be inserted through an opening. The stop may be adjustably mounted on the insertion tool.

5 In one embodiment the insertion tool comprises a handle.

The insertion tool may have a wound extending portion with a transverse dimension of from 3 to 35mm, preferably from 5 to 12mm.

10 The invention also provides a wound retractor which comprises

a proximal member for location externally of a wound opening;

15 the proximal member being movable relative to the retracting member to shorten the axial extent of the retracting member to laterally retract a wound opening.

The wound retractor may form part of the system of the invention.

20 The proximal member may comprise an annular ring means. The annular ring means may comprise an inner ring and an outer ring between which the retracting member may be led.

25 In one embodiment one of the rings defines a projection for location in a complimentary recess of the outer ring with the retracting member located therebetween. The projection may be a relatively tight fit in the recess to grip the retracting member therebetween. The projection may be locatable in the recess in a snap-fit manner. In one case the inner ring defines the projection and the outer ring defines the recess. Alternatively, the outer ring defines the projection and the inner ring defines the recess.

30

A system may comprise one or more valves to facilitate sealed access of an object through the retractor. The valve(s) may be mounted to the proximal member.

5 In one embodiment the retractor comprises a distal member coupled to a distal end of the retracting member. The distal member may comprise an O-ring.

The distal member may comprise an annular disc.

10 The distal member may be of a resilient material.

The retracting member may be flared distally outwardly.

15 The retractor may comprise means to seal a retracted wound opening. The sealing means may be provided externally of a wound opening. The sealing means may be mountable to the proximal member. The sealing means may comprise a cap.

The sealing means may comprise a valve to facilitate sealed access of an object through the sealing means. The object may comprise an instrument.

20 In one embodiment the retracting member comprises a sleeve to line a wound opening.

The invention also provides a method for introducing an element such as an instrument into a body cavity, the method comprising the steps of:-

25 making an incision in a body wall, the incision having a length to accommodate the element on retraction of the incision;

30 providing a wound retractor comprising a distal member, a proximal member and a retracting member extending at least between the distal member and the

proximal member, the retracting member being axially movable relative to the proximal member;

5 inserting the distal member through the incision such that the retracting member extends through the incision and the proximal member is located outside of the incision;

10 moving the proximal member relative to the retracting member to shorten the axial extent of the retracting member located between the distal member and the proximal member;

providing a valve;

15 mounting the valve to the reactor;

introducing an element through the valve; and

20 introducing the element through the retracted incision and into the body cavity.

Typically the body cavity is an abdominal cavity.

The length of the incision may be from 3 to 35 millimetres, typically from 5 to 15mm.

25 In another aspect the invention provides a method for retracting an incision comprising the steps of:-

30 making an incision in a body wall;

providing a wound retractor comprising a distal member and a retracting member extending from the distal member;
providing an insertion tool having a receiver for the retractor;

5 mounting the retractor to the receiver of the insertion tool;

inserting the insertion tool with the retractor mounted thereon through the incision;

10 deploying the retractor in the incision; and

withdrawing the insertion tool from the incision.

15 In one embodiment the retracting member comprises a proximal portion located proximally of the proximal member and a distal portion located distally of the proximal member, and the method comprises the step of decoupling the proximal portion from the distal portion after retraction of the wound opening. The proximal portion may be decoupled from the distal portion by a cutting action.

20 In one embodiment the proximal member comprises an inner ring and an outer ring, and the method comprises the step of fitting the inner ring relative to the outer ring to grip the retracting member therebetween. The inner ring may be snap-fitted relative to the outer ring after retraction of the wound opening. The inner ring may be fitted relative to the outer ring after retraction of the wound opening.

25 The method may comprise the step of snap-fitting the inner ring relative to the outer ring which decouples the proximal portion of the retracting member from the distal portion.

In embodiment the method comprises the step of mounting the retractor to an insertion tool, and the insertion tool is inserted into the wound opening to insert the retractor into the wound opening.

5 The incision may be made by the insertion tool.

The method may comprise the step of sealing the retracted wound opening.

In another aspect the invention provides a wound retractor comprising:-

10

a retracting member for insertion into a wound opening; and

a proximal member for location externally of a wound opening;

15 the proximal member being movable relative to the retracting member to shorten the axial extent of the retracting member to laterally retract a wound opening.

In one embodiment the proximal member comprises an annular ring means.

20 In one case the annular ring means comprises an inner ring and an outer ring between which the retracting member may be lead. One of the rings may define a projection for location in a complimentary recess of the outer ring with the retracting member located therebetween. The projection may be a relatively tight fit in the recess to grip the retracting member therebetween. In one arrangement the projection is
25 locatable in the recess in a snap-fit manner.

In one embodiment the inner ring defines the projection and the outer ring defines the recess.

30 Alternatively the outer ring defines the projection and the inner ring defines the recess.

In one embodiment the proximal member comprises one or more valves to facilitate sealed access of an object through the proximal member.

5 In an aspect of the invention the retractor comprises a distal member coupled to a distal end of the retracting member. The distal member may comprise an O-ring. Alternatively the distal member comprises an annular disc. The distal member may be of a resilient material.

10 In one embodiment the retracting member is flared distally outwardly.

In one aspect the retractor comprises means to seal a retracted wound opening. The sealing means may be provided externally of a wound opening.

15 Typically, the sealing means is mountable to the proximal member. The sealing means may comprise a cap.

In one embodiment the sealing means comprises one or more valves to facilitate sealed access of an object through the sealing means.

20

In one arrangement the retracting member comprises a sleeve to line a wound opening.

25 The invention also provides a method of retracting a wound opening, the method comprising the steps of:-

providing a wound retractor comprising a retracting member, and a proximal member;

30 inserting the retracting member into a wound opening;

locating the proximal member externally of the wound opening; and

moving the proximal member relative to the retracting member to shorten the axial extent of the retracting member to laterally retract the wound opening.

5

In one embodiment the retracting member comprises a proximal portion located proximally of the proximal member and a distal portion located distally of the proximal member, and the method comprises the step of decoupling the proximal portion from the distal portion after retraction of the wound opening.

10

The proximal portion may be decoupled from the distal portion by a cutting action.

15

In one arrangement the proximal member comprises an inner ring and an outer ring, and the method comprises the step of snap-fitting the inner ring relative to the outer ring to grip the retracting member therebetween. The inner ring may be snap-fitted relative to the outer ring after retraction of the wound opening.

20

In one embodiment the step of snap-fitting the inner ring relative to the outer ring decouples the proximal portion of the retracting member from the distal portion.

In another aspect the method comprises the step of mounting the retracting member to an obturator, and the obturator is inserted into the wound opening to insert the retracting member into the wound opening.

25

Typically, the method comprises the step of sealing the retracted wound opening.

Brief Description of the Drawings

30

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a cross-sectional, side view of a wound retractor according to the invention, in use;

5 Fig. 2 is a perspective view of the retractor of Fig. 1 being inserted into a wound opening;

Figs. 3 to 5, 7 and 9 are cross-sectional, side views of the wound opening being retracted using the retractor of Fig. 1

10

Fig. 6 is a plan view of the retractor and the wound opening of Fig. 5;

Fig. 8 is a plan view of the retractor and the wound opening of Fig. 7;

15 Figs. 10 and 11 are views similar to Figs. 5 and 6 of a wound opening being retracted in an alternative manner using the retractor of Fig. 1;

Figs. 12 and 13 are cross-sectional, side views of a wound opening being retracted using the retractor of Fig. 1 and an obturator;

20

Figs. 14 and 15 are cross-sectional, side views of a wound opening being retracted using the retractor and the obturator of Figs. 12 and 13 and a pusher;

25 Fig. 16 is a cross-sectional, side view of the retractor of Fig. 1 and a sealing cap;

Figs. 17 and 19 are perspective views of a distal end of other wound retractors according to the invention;

30 Figs. 20 to 22 are perspective views of an inner ring part of other wound retractors according to the invention;

Fig. 23 is a cross-sectional, side view of another wound retractor according to the invention;

5 Figs. 24 to 26 are cross sectional views of a retractor system;

Fig. 27 is a view of an introducer tool according to the invention;

10 Figs. 28 to 30 are views of a retractor distal ring;

Figs. 31 to 33 are views of another introducer tool;

Figs. 34 and 35 are views of a further introducer tool;

15 Figs. 36 to 40 are cross sectional views of the tool of Figs. 34 and 35, in use;

Figs. 41 and 42 are cross sectional views of another introducer tool, in use;

20 Figs. 43 to 46 are cross sectional views of an introducer tool, in use; and

Figs. 47 to 50 are cross sectional views of another introducer tool, in use.

Detailed Description

25 Referring to Figs. 1 to 16, there is illustrated a wound retractor 1 comprising a proximal member 2 for location, in use, externally of a wound opening 3, a retracting member 4 for insertion into the wound opening 3, and a distal member 5 coupled to a distal end of the retracting member 4.

30 In this case, the retracting member 4 is provided in the form of a sleeve of flexible, polymeric film material which lines the sides of the wound opening 3 when the

retractor 1 is in use (Fig. 1). The distal member 5 in this case comprises a resilient O-ring.

5 The proximal member 2 is provided, in this case, in the form of an annular ring means having an inner ring 6 and an outer ring 7 with the retracting member 4 lead between the rings 6, 7. The inner ring 6 has a circular cross-section and the outer ring 7 defines a "C"-shaped recess. In this manner a projecting portion of the inner ring 6 may be located in a snap-fit manner in the complimentary recess of the outer ring 7. The inner ring 6 is configured to be a relatively tight fit in the recess of the
10 outer ring 7 to securely grip the retracting member 4 between the two rings 6, 7.

In use, a relatively small incision 8 is made in an abdominal wall 9 to form the wound opening 3. A typical length for the incision 8 to accommodate instruments and/or for specimen removal is from 3 to 35 millimetres. For an instrument,
15 typically the incision is length will be in the range of 5 to 15 millimetres. The resilient distal O-ring 5 is then manipulated into an elongate, oblong shape by squeezing the distal O-ring 5 to facilitate insertion of the distal O-ring 5 through the wound opening 3 (Fig. 2), until the distal O-ring 5 is fully located within the abdominal cavity 10 and the sleeve 4 lines the wound opening 3 (Fig. 3). The sleeve
20 4 is then pulled upwardly to cause the distal O-ring 5 to engage with the internal surface of the abdominal wall 9 (Fig. 4).

Next the proximal member 2 is threaded over the sleeve 4 with the sleeve 4 passing between the inner ring 6 and the outer ring 7. The proximal member 2 is then moved
25 downwardly relative to the sleeve 4 by pulling the sleeve 4 taut upwardly and pushing the proximal member 2 downwardly (Figs. 5 and 6). This action of moving the proximal member 2 relative to the sleeve 4 shortens the axial extent of the portion of the sleeve 4 which lines the wound opening 3, and thereby results in lateral retraction of the wound opening 3, as illustrated in Figs. 7 and 8.

The tight-fit arrangement of the inner ring 6 in the recess of the outer ring 7 ensures that the sleeve 4 is securely gripped between the rings 6, 7. Thus the proximal member 2 acts as a lock to maintain the wound opening 3 in the retracted configuration illustrated in Figs. 7 and 8.

5

The portion of the sleeve 4 proximally of the rings 6, 7 is thereafter surplus to requirements and may be removed, for example by cutting it away (Fig. 9).

10 By engaging the internal surface of the abdominal wall 9, the distal O-ring 5 acts as an anchor to maintain the retractor 1 in position in the wound opening 3, during use.

An alternative method of using the wound retractor 1 to retract the wound opening 3 is illustrated in Figs. 10 and 11. In this case, the inner ring 6 and the outer ring 7 are moved downwardly relative to the sleeve 4 before the inner ring 6 is snap-fitted into position in the recess of the outer ring 7. The inner ring 6 is located above the outer ring 7.

15 The inner ring 6 is pushed downwardly, which causes the outer ring 7 to move downwardly also, while pulling the sleeve 4 taut upwardly until the outer ring 7 engages the external surface of the abdominal wall 9. Further pushing of the inner ring 6 downwardly then causes the inner ring 6 to snap into position in the recess of the outer ring 7 securely gripping the sleeve 4 between the rings 6, 7. The action of the inner ring 6 snapping into position in the recess of the outer ring 7 may be configured to cut the sleeve 4 for subsequent removal of the surplus proximal portion of the sleeve 4.

25

Referring to Figs. 12 to 15 there is illustrated another method of using the wound retractor 1. In this case the retractor 1 is mounted to a blunt obturator 11 before insertion into the wound opening 3. The obturator 11 and the retractor 1 are then inserted together through the wound opening 3 until the distal O-ring 5 is fully

30

located within the abdominal cavity 10 and the sleeve 4 lines the wound opening 3 (Fig. 12).

5 The distal O-ring 5 is engaged with the internal surface of the abdominal wall 9, and the proximal member 2 is moved downwardly relative to the sleeve 4 (Fig. 13), in a manner similar to that described previously with reference to Figs. 4 to 8. The obturator 11 may then be removed from the wound opening 3. The proximal member 2 acts as a lock thereafter to maintain the wound opening 3 in the retracted configuration.

10 It has been found that the use of the obturator 11 may assist in deployment of the wound retractor 1. In particular, retraction of the wound opening 3 by means of the sleeve 4 during the set-up procedure is not required when the obturator 11 is employed.

15 A sharp obturator could alternatively be employed in a similar manner to that described previously with reference to Figs. 12 and 13. A sharp obturator has the additional advantage that the initial incision 8 in the abdominal wall 9 could be made using the sharp obturator.

20 Figs. 14 and 15 illustrate a further method of retracting the wound opening 3 using the wound retractor 1, which is similar to the method described previously with reference to Figs. 12 and 13.

25 In this case, the retractor 1 is mounted to the obturator 11 before the inner ring 6 is snap-fitted into position in the recess of the outer ring 7. A tubular pusher 12 is slidably mounted around the obturator 11 for engagement with the inner ring 6.

30 By pushing on the pusher 12 downwardly while pulling the sleeve 4 taut upwardly, the rings 6, 7 are moved downwardly until the outer ring 7 engages the external surface of the abdominal wall 9. Further pushing of the pusher 12 downwardly then

causes the inner ring 6 to snap into position in the recess of the outer ring 7, and simultaneously causes cutting of the sleeve 4.

5 The sleeve 4 is thus securely gripped between the rings 6, 7 to maintain the wound opening 3 in the retracted configuration. Also the surplus proximal portion of the sleeve 4 which has been cut away may be removed.

10 The wound opening 1 may include means to seal the retracted wound opening 3. For example, Fig. 16 illustrates a sealing cap 13 releasably mounted to the proximal member 2 externally of the wound opening 3. The cap 13 may be temporarily mounted to the proximal member 2 to maintain a gas-tight seal of the retracted wound opening 3, for example to maintain pneumoperitoneum within the abdominal cavity 10. If it is desired to access the abdominal cavity 10, and/or to remove matter from within the abdominal cavity 10, the cap 13 can be quickly and easily removed to reveal the retracted wound opening 3.

15 It will be appreciated that various other sealing means may alternatively be provided with the wound retractor 1. For example, one or more valves may be included to facilitate sealed access of an object, such as an instrument, through the retracted wound opening 3.

20 The distal end of the sleeve 4 may be flared distally outwardly towards the distal O-ring 20, as illustrated in the wound retractor 25 of Fig.17. This arrangement enhances the anchoring of the retractor 25 in position in the wound opening 3 with less risk of the distal O-ring 20 being pulled up through the wound opening 3, during use.

25 A variety of different configurations are possible for the distal member of the wound retractor within the scope of this invention. For example, the distal member may be a standard O-ring 21, as illustrated in the wound retractor 26 of Fig. 18, or the distal member may be provided in the form of a flexible, annular disc 22, as illustrated in

30

the wound retractor 27 of Fig. 19. It has been found that the disc 22 provides enhanced anchoring of the retractor 27 in position in the wound opening 3, during use.

5 In addition, a variety of different configurations are possible for the proximal member of the wound retractor within the scope of the invention. For example, the inner ring of the proximal member may be provided in the form of a standard O-ring 30, as illustrated in Fig. 20. Alternatively one or more valves, such as a lip seal 32, may be provided as part of the inner ring 31, as illustrated in Fig. 21 to facilitate
10 sealed access of an object, such as an instrument, through the proximal member. As a further alternative, the proximal member may comprise a closed cap 33 (Fig. 22) to completely seal the retracted wound opening 3, for example, to maintain pneumoperitoneum in the abdominal cavity 10.

15 It will be appreciated that the configuration of the proximal member 2 may be reversed. For example, an inner ring 41 may define a "C"-shaped recess and an outer ring 40 may have a circular cross-section, as illustrated in Fig. 23.

Referring now to Figs. 24 to 26 another modular system is illustrated in which a
20 valve 50 is releasably mounted to a retractor 51. The retractor 51 may be similar to the retractors described above, like parts being assigned the same reference numerals. The retractor 51 may have a proximal ring member 52 with a recess 53 to receive the valve 50. The sleeve 4 may be hooked over the proximal ring member 52, as illustrated. An instrument shaft 55 can readily pass through the valve 50 and
25 the retractor 51. At least a section 56 of the shaft 55 can be bent or steered almost immediately distal of the retractor 51.

The access ports of the invention provide controlled radial expansion. Greater access is achieved using smaller incision. The incision size can be varied as required, for
30 example for a laparoscopic procedure.

The retractor ensures that there is substantially no gas leakage from the wound margins and that it cannot be inadvertently pulled out of the incision

- 5 The retractor can be used to seal any incision and without the requirement of a secondary sealing method such as suturing.

10 The retractor has minimum intra-abdominal profile. There is more working space in the abdomen which may be very important for some procedures such as pelvic surgery. The retractor also provides perineal access for operations such as radical prostatectomy.

15 The retractor also protects a wound from infection and cancer seeding. Upon removal, all areas of potential contamination are isolated from the incision.

20 The retractor also provides reduced extra-abdominal profile. This increases the effective working length of an instrument and provides a greater working area outside the abdomen.

- 25 The retractor will also increase the freedom of movement of conventional laparoscopic instruments during procedures.

30 The retractor may be inserted through the abdominal wall as described below. An initial small incision 90 which is in the range 3mm to 35mm may be made in the abdominal wall 97 and an inner distal ring 91 of the retractor may be attached to an insertion tool 92 as illustrated in Fig. 27. The ring 91 is flexible and can be stretched or bent as illustrated for ease of insertion through the incision 90. The ring 91 may be retained in the stretched/bent insertion configuration using locating grooves 93 in the insertion tool 92. Alternatively or additionally as illustrated in Figs. 28 to 30 the ring 91 may be split into a number (in this case 4) of sections 95 with an inner thread

96 passing between and linking the sections 95. The ring 91 can be bent as illustrated to reduce the profile in the insertion configuration. The system is biased so that the ring 91 re-forms into the circular configuration once released on insertion.

5 In some cases (Figs. 31 to 33) the ring 91 may be inserted through the incision using a blunted or round-nosed obturator tool 100.

Alternatively as illustrated in Figs. 34 and 35 the ring 91 may be inserted using an obturator/trocar tool 101 with a leading cutting blade 102. In this case, as illustrated
10 in Figs. 36 to 40, the tool 101 itself makes an incision in the abdominal wall, allowing the distal ring 91 of the retractor to be delivered and deployed, as illustrated.

In some cases, as illustrated in Figs. 41 and 42 an insertion tool 110 may have a stop
15 115 thereon to limit the extent by which the tool can project into the patient. The stop 115 may be fixed, or adjustable in position. The adjustment of the stop 115 may be used to facilitate different thicknesses of abdomen. Such adjustment could be achieved using any suitable means such as a screw thread or ratchet system. The adjustment may be rendered at least partially automatic by using a spring loaded type
20 system.

An alternative insertion tool 120 is illustrated in Figs. 43 to 46. In this case the leading end 121 of the tool 120 is blunted and is inserted through a pre-made incision
25 90. The distal ring 91 of the retractor is retained in a groove 122 at the distal end of the tool 120.

In an alternative embodiment illustrated in Figs. 47 to 50 an introducer tool 130 has an integral blade 135 which is lined up to the desired location and the tool 130 is pushed through to make a leading incision 90 in the abdominal wall 97.
30

The introducer tool may be any suitable size, however it may be of a size similar to that of a conventional trocar i.e. typically 3 to 35 mm.

5 The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

Claims

1. A wound retractor system comprising:-
 - 5 a retractor having a retracting member for insertion into a wound opening; and
 - an insertion tool for inserting or assisting the insertion of or deployment of the retracting member in a wound opening.
- 10 2. A system as claimed in claim 1 wherein the insertion tool has a receiver for mounting the retractor to the insertion device.
- 15 3. A system as claimed in claim 2 wherein the retractor comprises a distal portion and the receiver is adapted for mounting the distal portion to the insertion tool.
- 20 4. A system as claimed in claim 3 wherein the receiver comprises a groove for receiving the distal portion of the retractor.
5. A system as claimed in claim 3 or 4 wherein the distal portion comprises a distal ring member mounted to the retracting member.
- 25 6. A system as claimed in claim 5 wherein the distal ring member is of flexible material.
7. A system as claimed in claim 5 or 6 wherein the ring member is of elastomeric material.
- 30 8. A system as claimed in any preceding claim wherein the insertion tool comprises an elongate member having a distal end.

9. A system as claimed in claim 8 wherein the distal end of the insertion tool has a cutting blade for forming an incision.
- 5 10. A system as claimed in claim 8 or 9 wherein the retractor comprises a proximal ring member and the insertion tool has a pusher to push the proximal member towards a distal member to shorten the axial extent between the proximal and distal ring members.
- 10 11. A system as claimed in claim 10 wherein the pusher comprises a blade.
12. A system as claimed in any preceding claim wherein the insertion tool comprises a stop for limiting the extent to which the tool may be inserted through an opening.
- 15 13. A system as claimed in claim 12 wherein the stop is adjustably mounted on the insertion tool.
14. A system as claimed in any preceding claim wherein the insertion tool comprises a handle.
- 20 15. A system as claimed in any preceding claim wherein the insertion tool has a wound extending portion with a transverse dimension of from 3 to 35mm.
- 25 16. A system as claimed in claim 15 wherein the transverse dimension of the wound extending portion is from 5 to 12mm.
17. A system as claimed in any preceding claim wherein the wound retractor comprises
- 30 a proximal member for location externally of a wound opening;

the proximal member being movable relative to the retracting member to shorten the axial extent of the retracting member to laterally retract a wound opening.

- 5 18. A system as claimed in claim 17 wherein the proximal member comprises an annular ring means.
- 10 19. A system as claimed in claim 18 wherein the annular ring means comprises an inner ring and an outer ring between which the retracting member may be lead.
- 15 20. A system as claimed in claim 19 wherein one of the rings defines a projection for location in a complimentary recess of the outer ring with the retracting member located therebetween.
- 20 21. A system as claimed in claim 20 wherein the projection is a relatively tight fit in the recess to grip the retracting member therebetween.
- 20 22. A system as claimed in claim 20 or 21 wherein the projection is locatable in the recess in a snap-fit manner.
- 25 23. A system as claimed in any of claims 20 to 22 wherein the inner ring defines the projection and the outer ring defines the recess.
- 25 24. A system as claimed in any of claims 20 to 22 wherein the outer ring defines the projection and the inner ring defines the recess.
- 30 25. A system as claimed in any of claims 17 to 24 wherein the proximal member comprises one or more valves to facilitate sealed access of an object through the proximal member.

26. A system as claimed in any of claims 17 to 25 wherein the retractor comprises a distal member coupled to a distal end of the retracting member.
- 5 27. A system as claimed in claim 26 wherein the distal member comprises an O-ring.
28. A system as claimed in claim 26 wherein the distal member comprises an annular disc.
- 10 29. A system as claimed in any of claims 26 to 28 wherein the distal member is of a resilient material.
30. A system as claimed in any of claims 17 to 29 wherein the retracting member is flared distally outwardly.
- 15 31. A system as claimed in any of claims 17 to 30 wherein the retractor comprises means to seal a retracted wound opening.
- 20 32. A system as claimed in claim 31 wherein the sealing means is provided externally of a wound opening.
- 25 33. A system as claimed in claim 31 or 32 wherein the sealing means is mountable to the proximal member.
34. A system as claimed in claim 33 wherein the sealing means comprises a cap.
- 30 35. A system as claimed in any of claims 31 to 34 wherein the sealing means comprises a valve to facilitate sealed access of an object through the sealing means.

36. A system as claimed in claim 35 wherein the object comprises an instrument.
37. A system as claimed in any of claims 17 to 36 wherein the retracting member
5 comprises a sleeve to line a wound opening.
38. A wound retractor system substantially as hereinbefore described with reference to the accompanying drawings.
- 10 39. A method for introducing an element such as an instrument into a body cavity, the method comprising the steps of:-
- making an incision in a body wall, the incision having a length to
accommodate the element on retraction of the incision;
- 15 providing a wound retractor comprising a distal member, a proximal member and a retracting member extending at least between the distal member and the proximal member, the retracting member being axially movable relative to the proximal member;
- 20 inserting the distal member through the incision such that the retracting member extends through the incision and the proximal member is located outside of the incision;
- 25 moving the proximal member relative to the retracting member to shorten the axial extent of the retracting member located between the distal member and the proximal member;
- providing a valve;
- 30 mounting the valve to the reactor;

introducing an element through the valve; and

introducing the element through the retracted incision and into the
body cavity.

5

40. A method as claimed in claim 39 wherein the body cavity is an abdominal cavity.

10

41. A method as claimed in claim 39 or 40 wherein the length of the incision is from 3 to 35 millimetres.

42. A method as claimed in any of claims 39 to 41 wherein the length of the incision is from 5 to 15 millimetres.

15

43. A method as claimed in any of claims 39 to 41 wherein the retracting member comprises a proximal portion located proximally of the proximal member and a distal portion located distally of the proximal member, and the method comprises the step of decoupling the proximal portion from the distal portion after retraction of the wound opening.

20

44. A method as claimed in claim 43 wherein the proximal portion is decoupled from the distal portion by a cutting action.

25

45. A method as claimed in any of claims 39 to 44 wherein the proximal member comprises an inner ring and an outer ring, and the method comprises the step of fitting the inner ring relative to the outer ring to grip the retracting member therebetween.

30

46. A method as claimed in claim 45 wherein the inner ring is snap-fitted relative to the outer ring after retraction of the wound opening.

47. A method as claimed in claim 45 or 46 wherein the inner ring is fitted relative to the outer ring after retraction of the wound opening.
- 5 48. A method as claimed in any of claims 43 to 47 wherein the step of snap-fitting the inner ring relative to the outer ring decouples the proximal portion of the retracting member from the distal portion.
- 10 49. A method as claimed in any of claims 39 to 48 wherein the method comprises the step of mounting the retractor to an insertion tool, and the insertion tool is inserted into the wound opening to insert the retractor into the wound opening.
- 15 50. A method as claimed in claim 49 wherein the incision is made by the insertion tool.
- 20 51. A method as claimed in any of claims 39 to 50 wherein the method comprises the step of sealing the retracted wound opening.
52. A method for retracting an incision comprising the steps of:-
- 25 making an incision in a body wall;
- providing a wound retractor comprising a distal member and a retracting member extending from the distal member;
- 30 providing an insertion tool having a receiver for the retractor;
- mounting the retractor to the receiver of the insertion tool;

inserting the insertion tool with the retractor mounted thereon through the incision;

5 deploying the retractor in the incision; and

 withdrawing the insertion tool from the incision.

10 53. A method as claimed in claim 52 wherein the distal member of the retractor is mounted to the receiver of the insertion tool.

 54. A method of retracting a wound opening substantially as hereinbefore described with reference to the accompanying drawings.

15

20

25

30

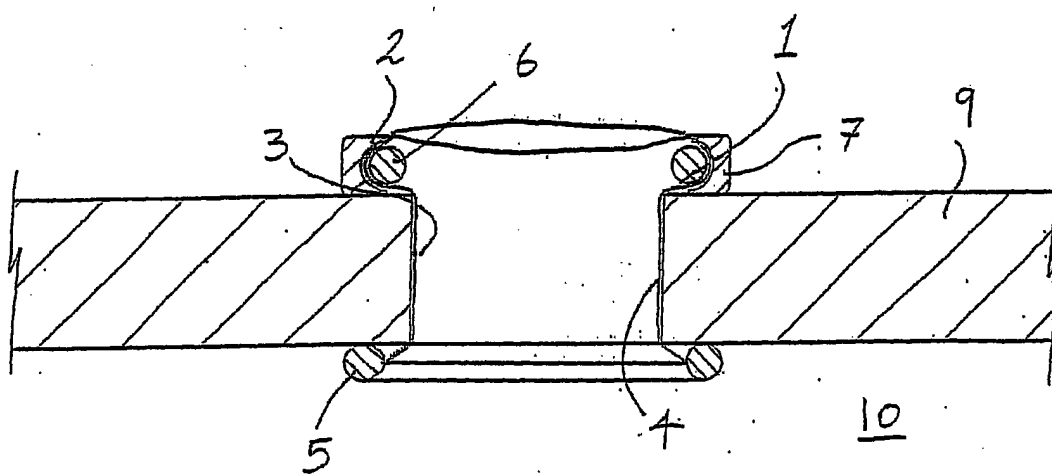


Fig. 1

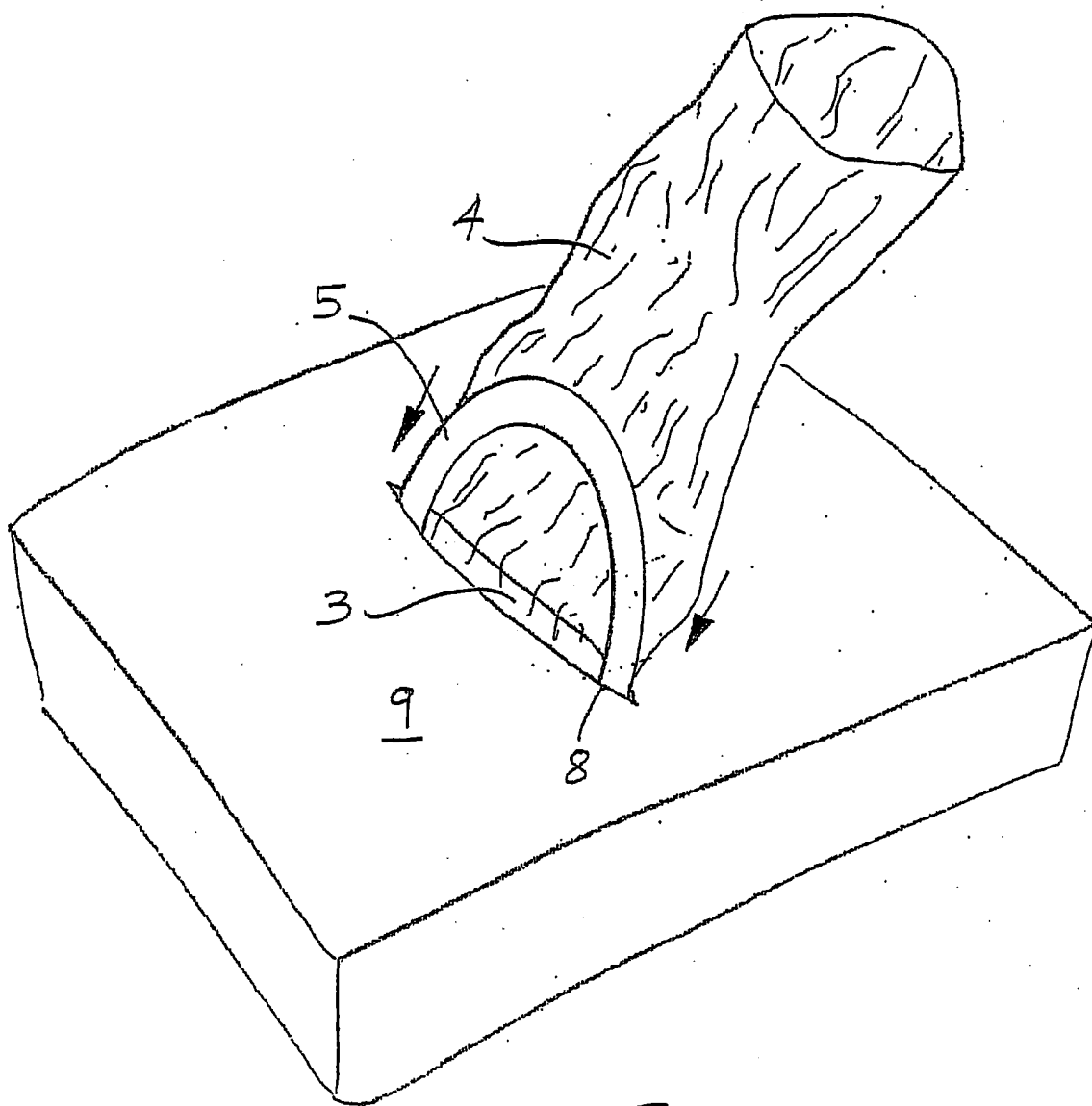


Fig. 2

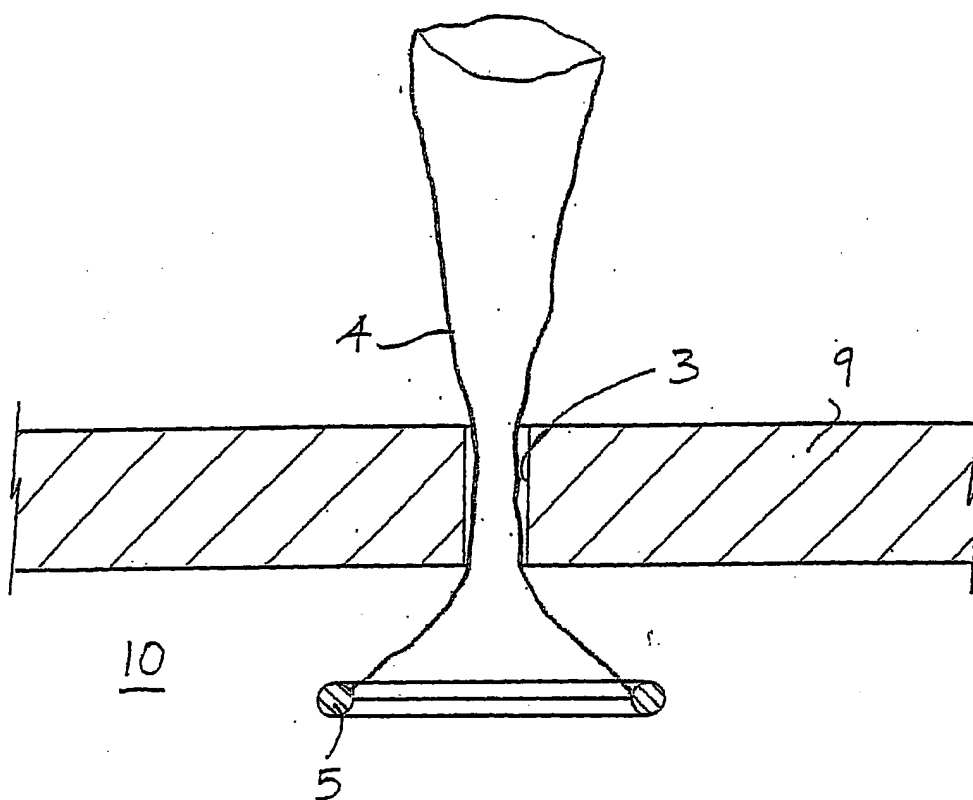


Fig. 3

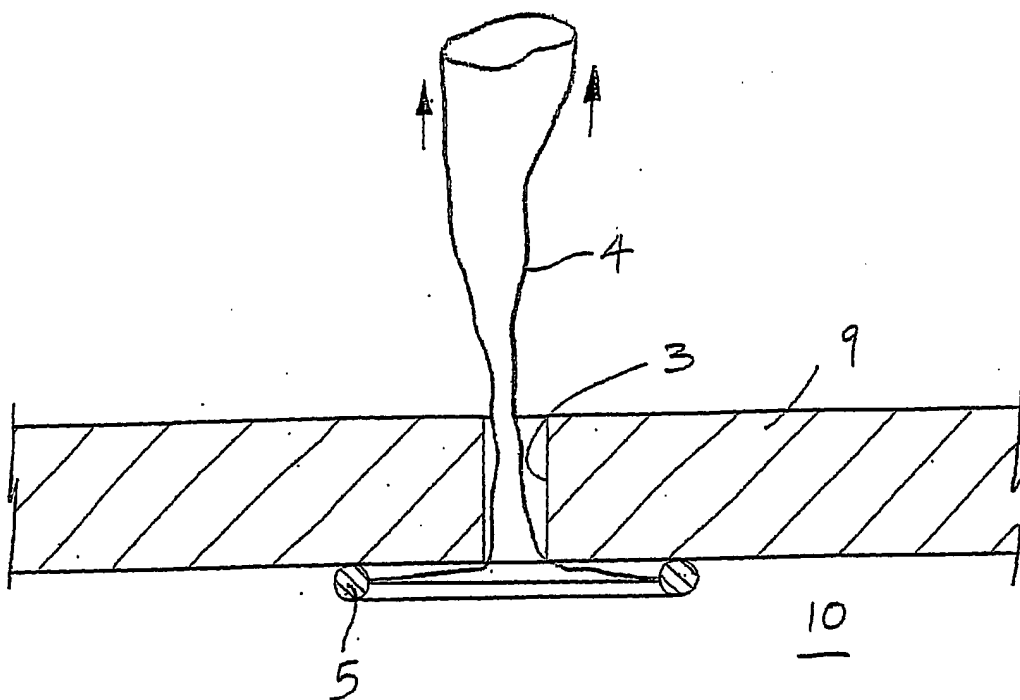


Fig. 4

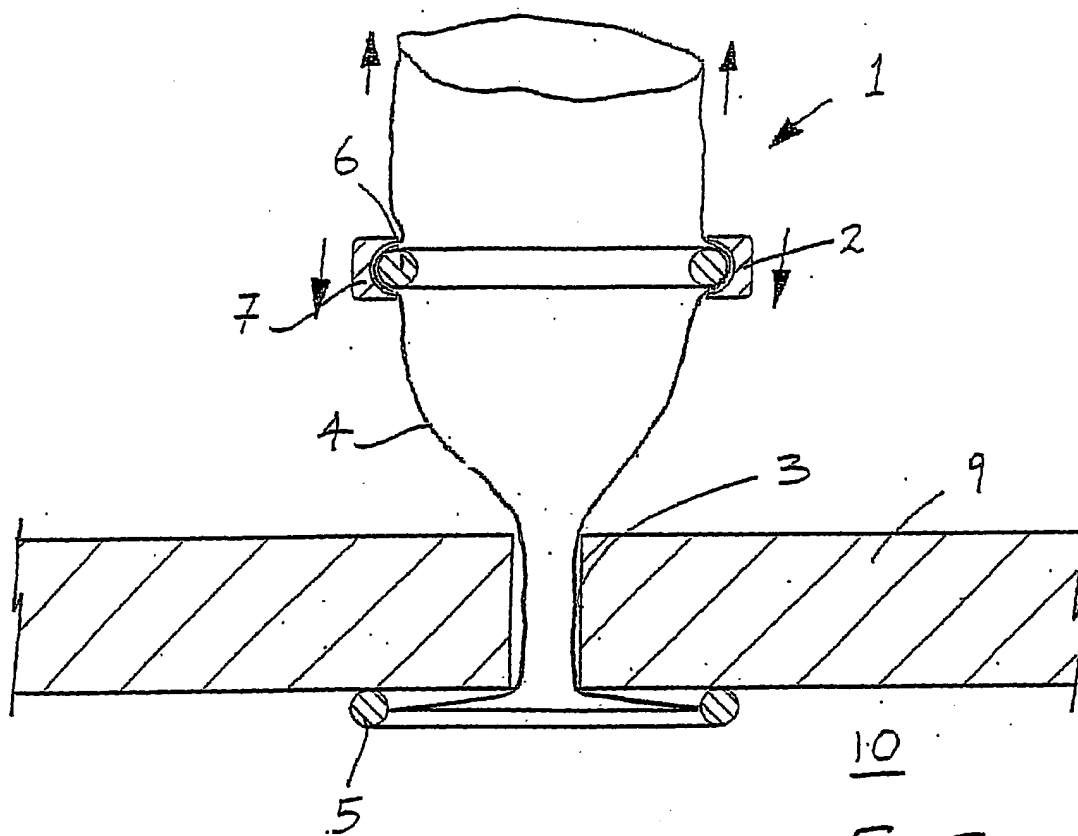


Fig. 5

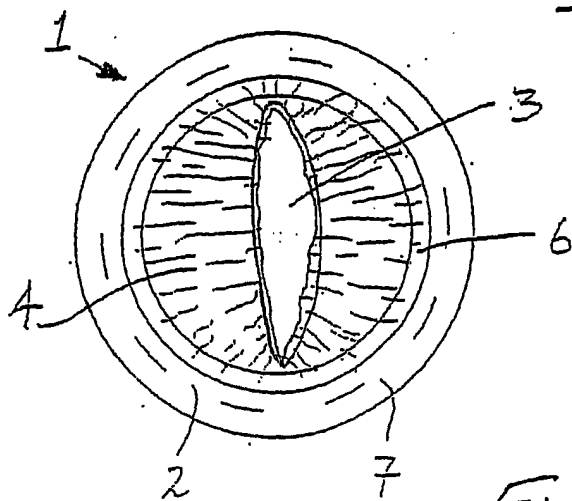


Fig. 6

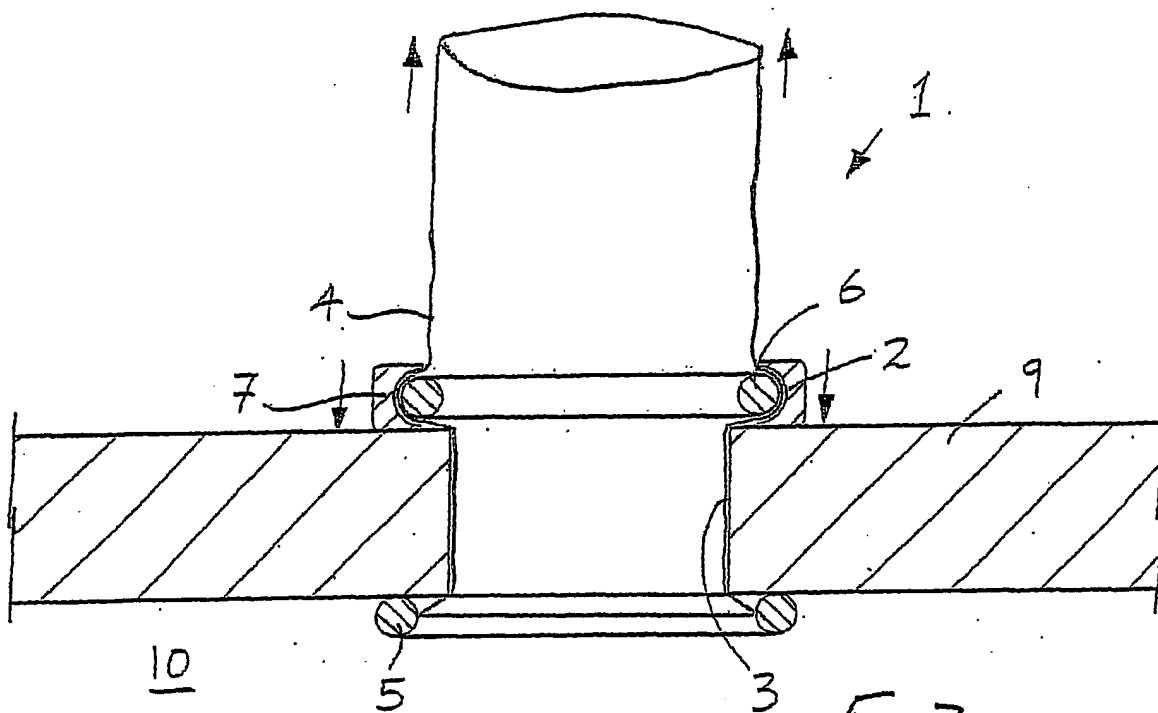


Fig. 7

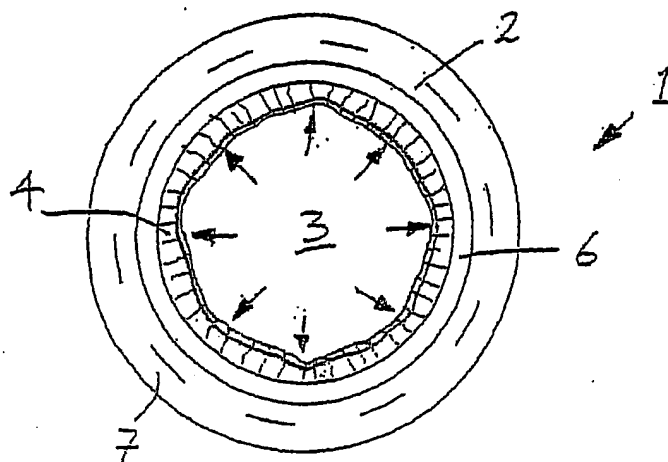


Fig. 8

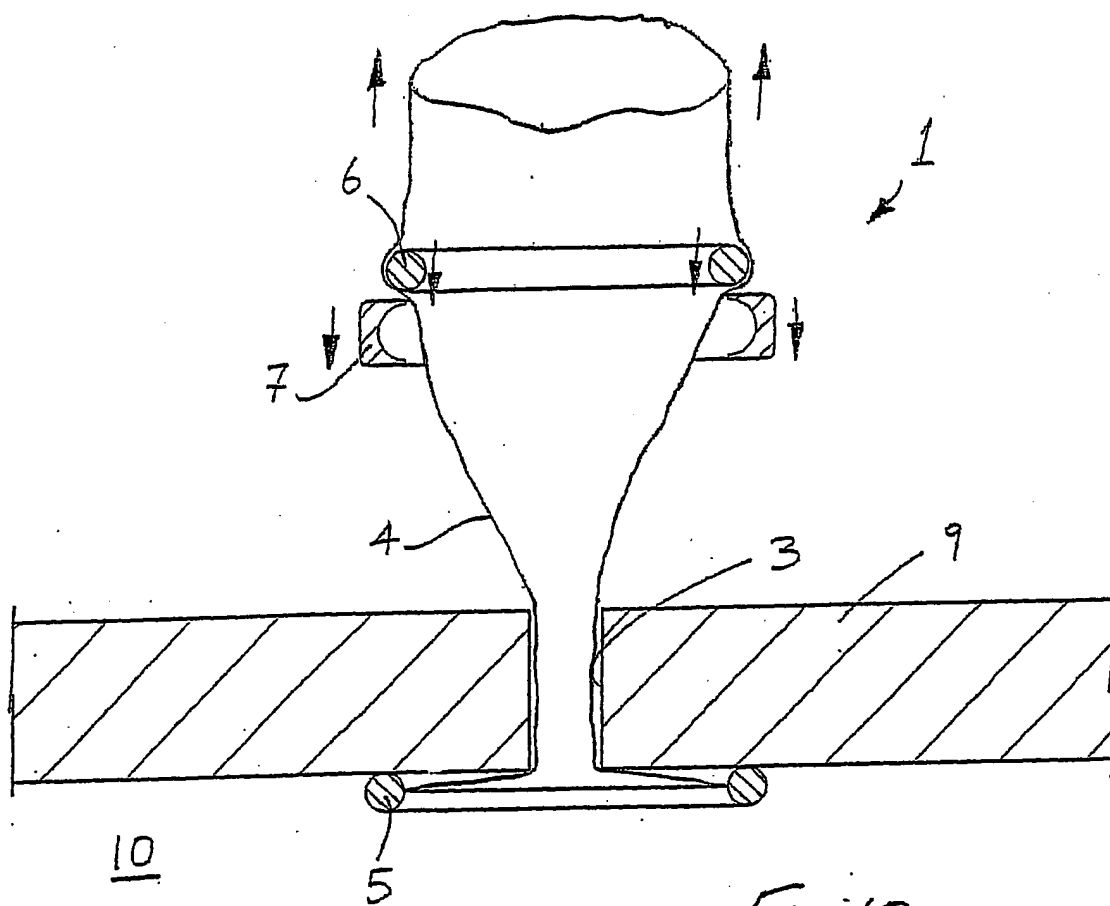


Fig. 10

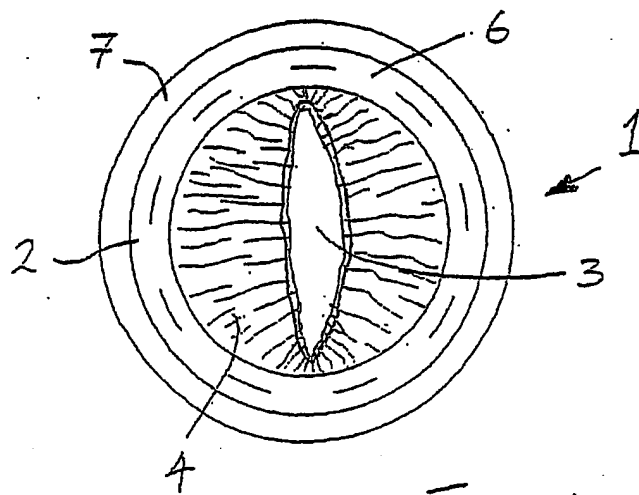
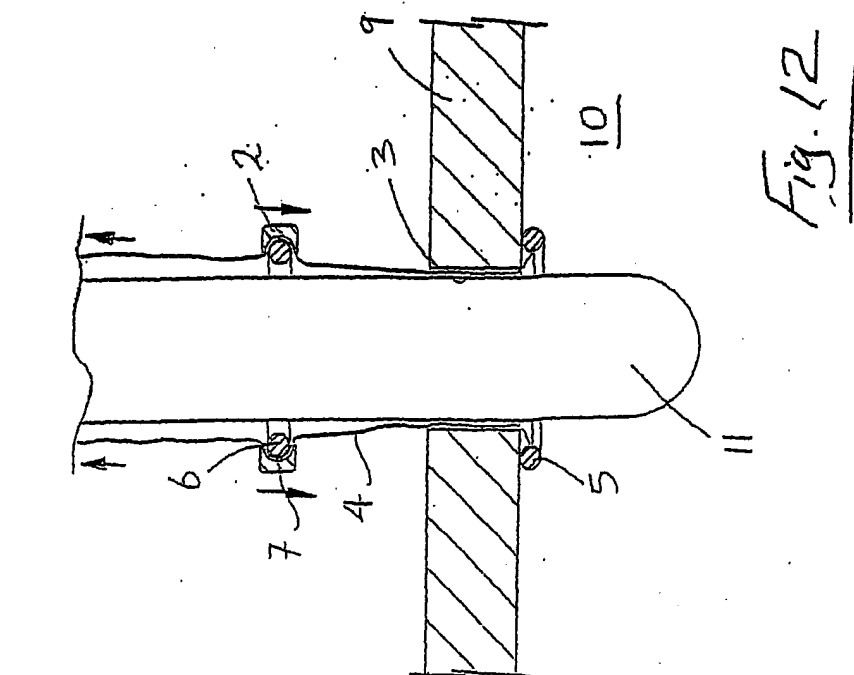
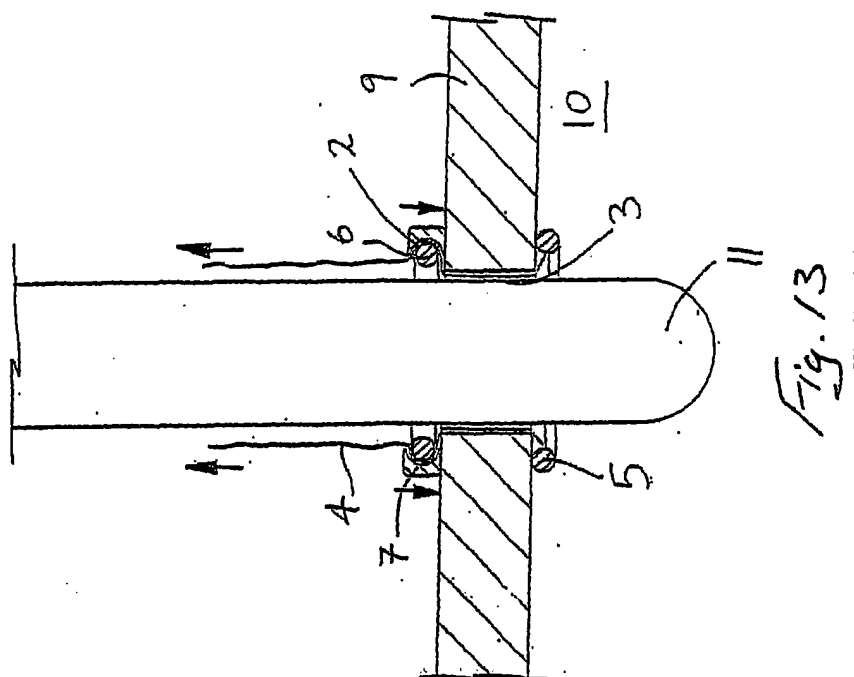
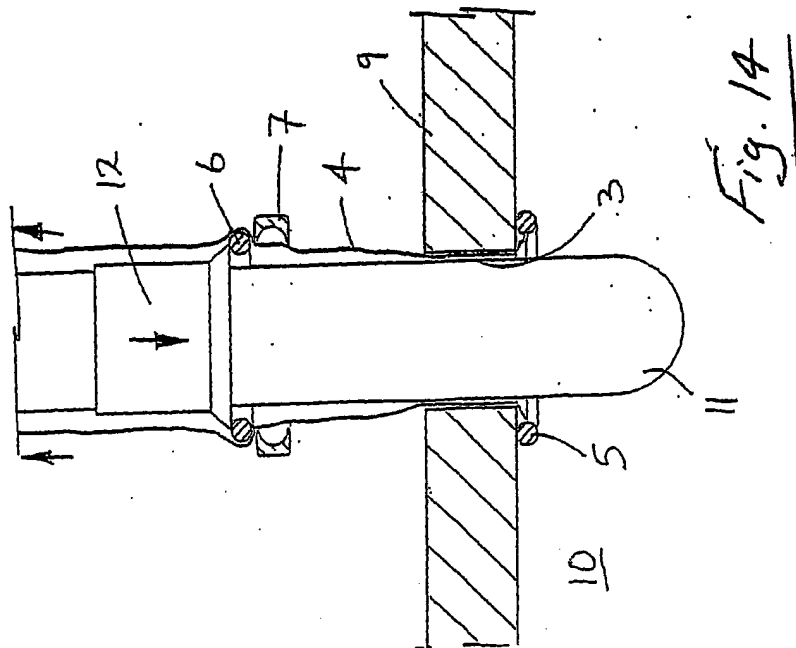
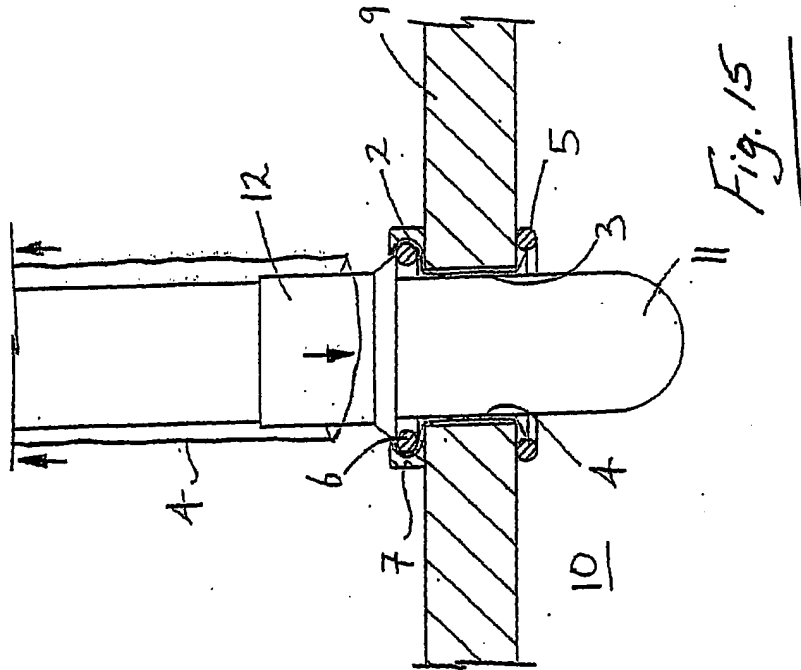


Fig. 11





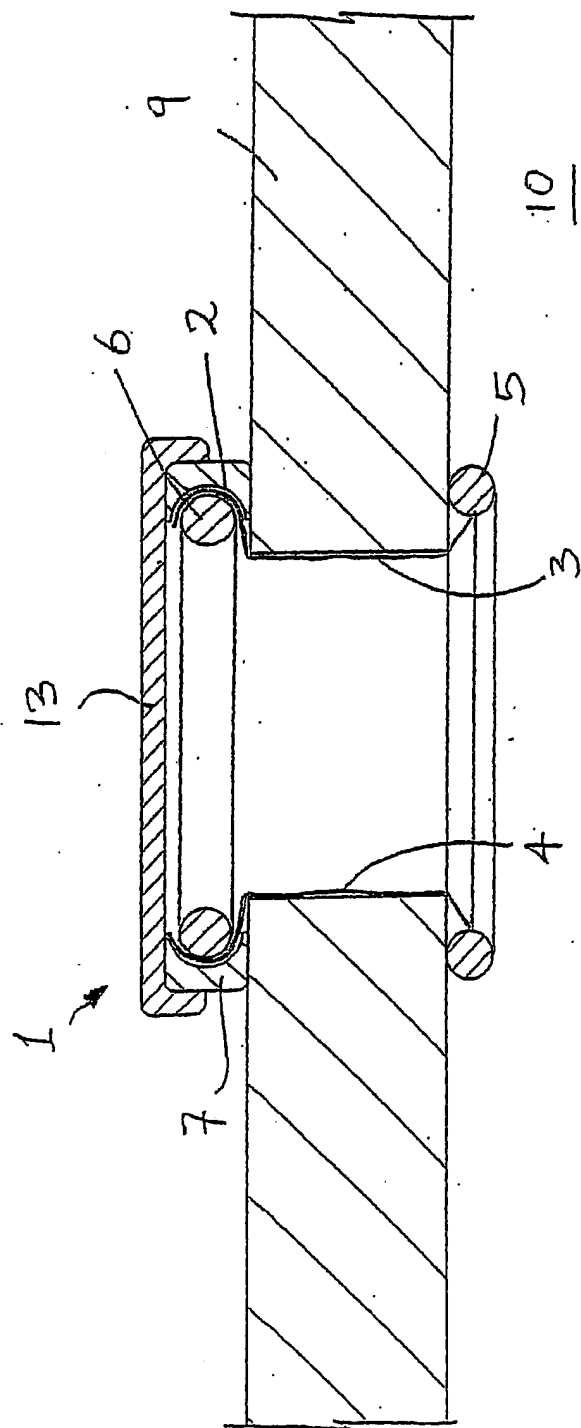


Fig. 16

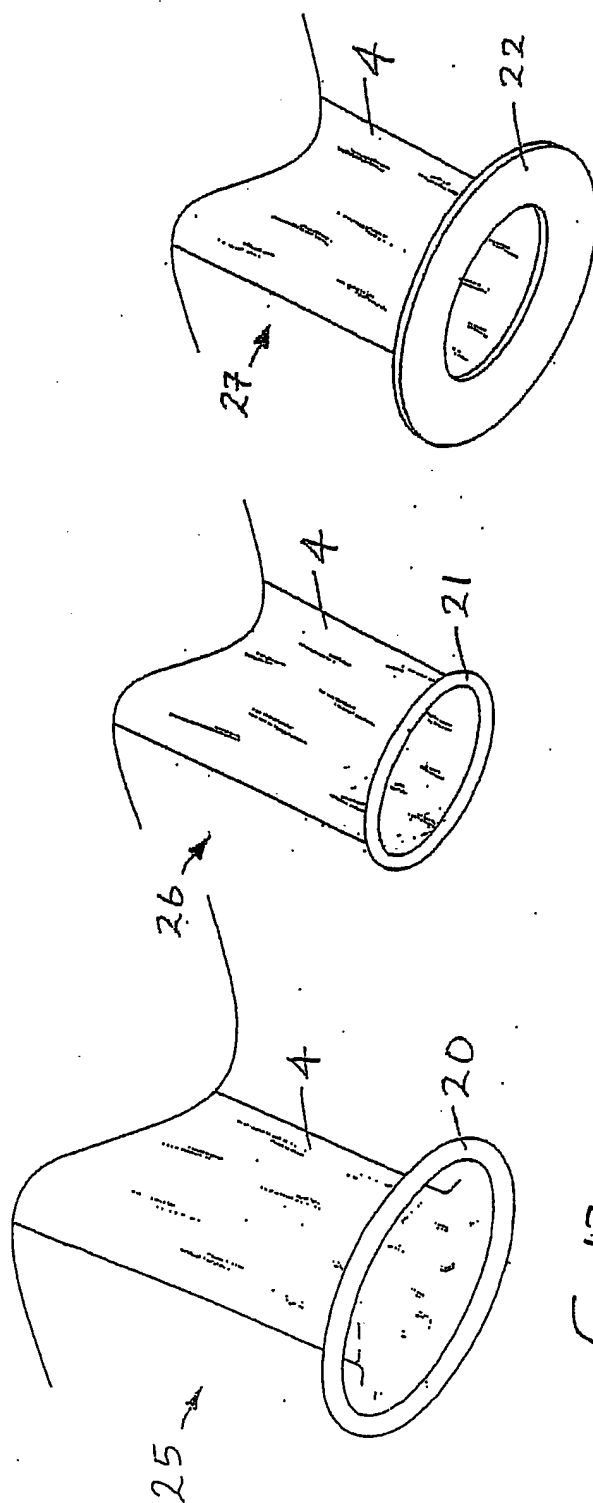


Fig. 17

Fig. 18

Fig. 19

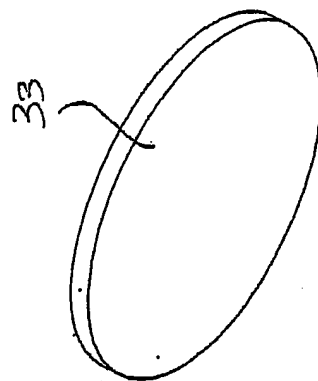


Fig. 22

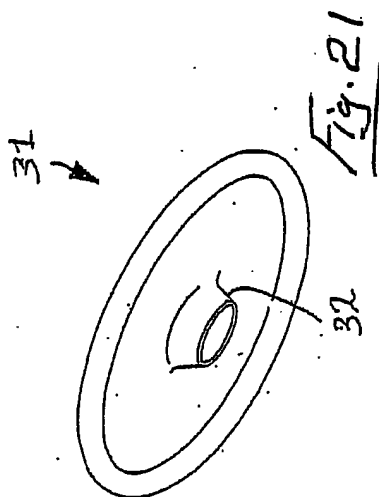


Fig. 21

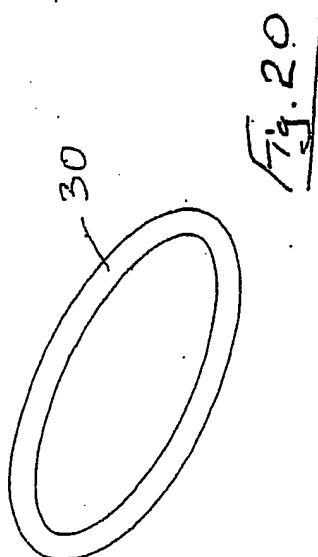


Fig. 20

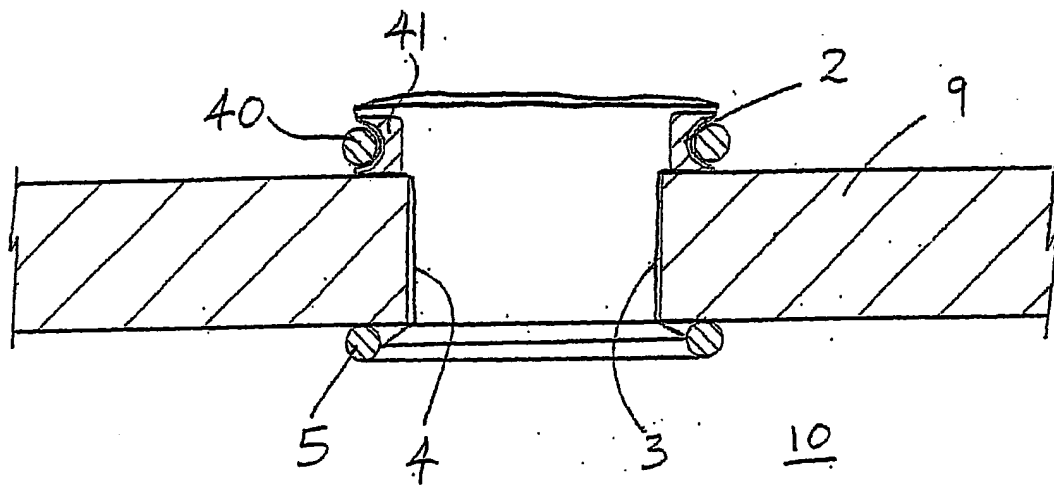


Fig. 23

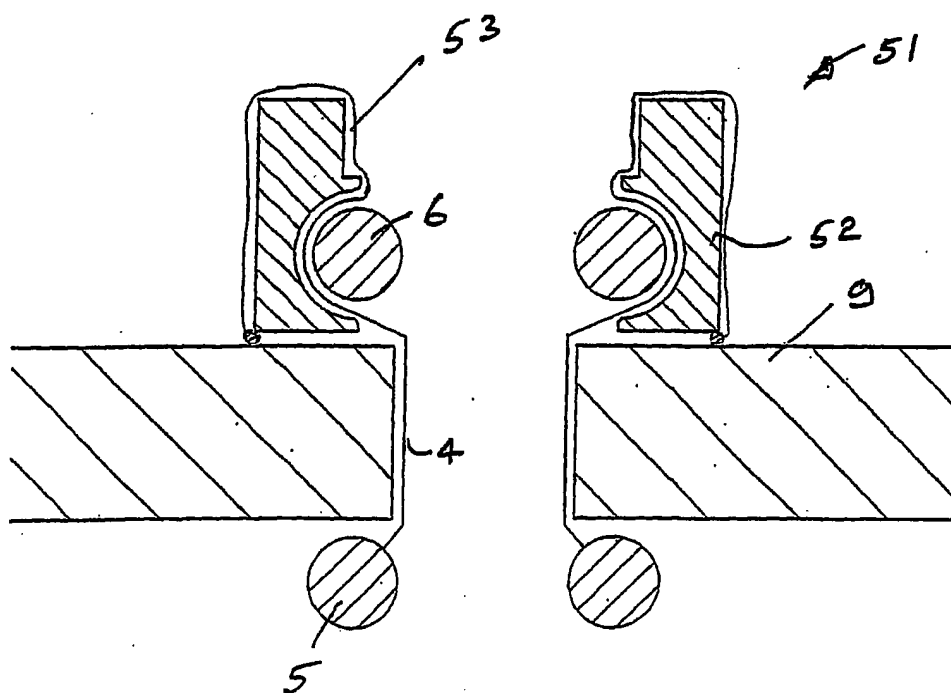
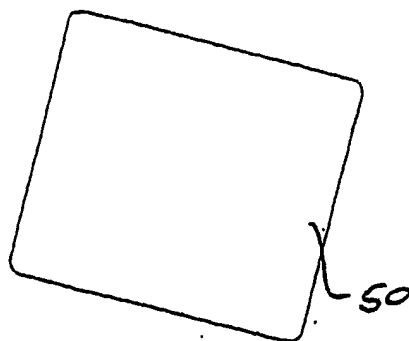


Fig. 24

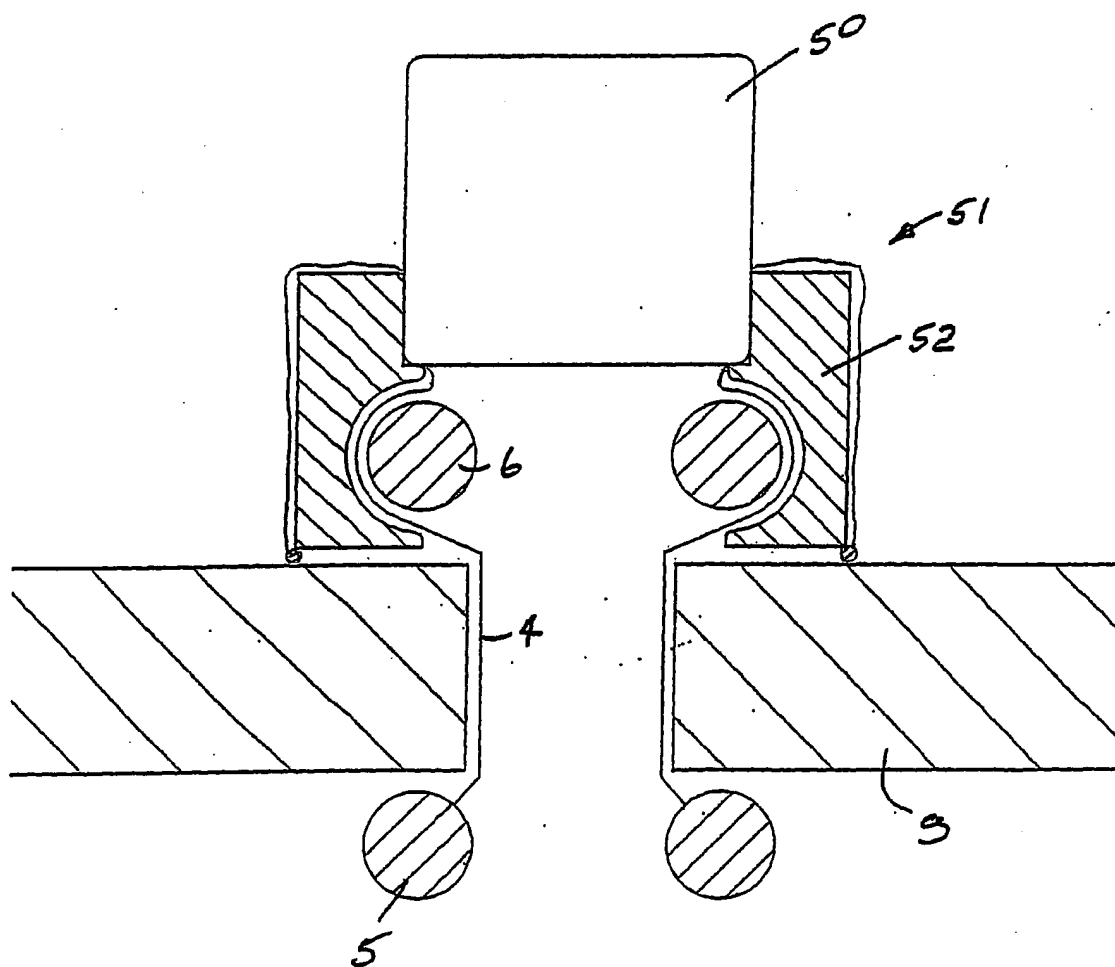


Fig. 25

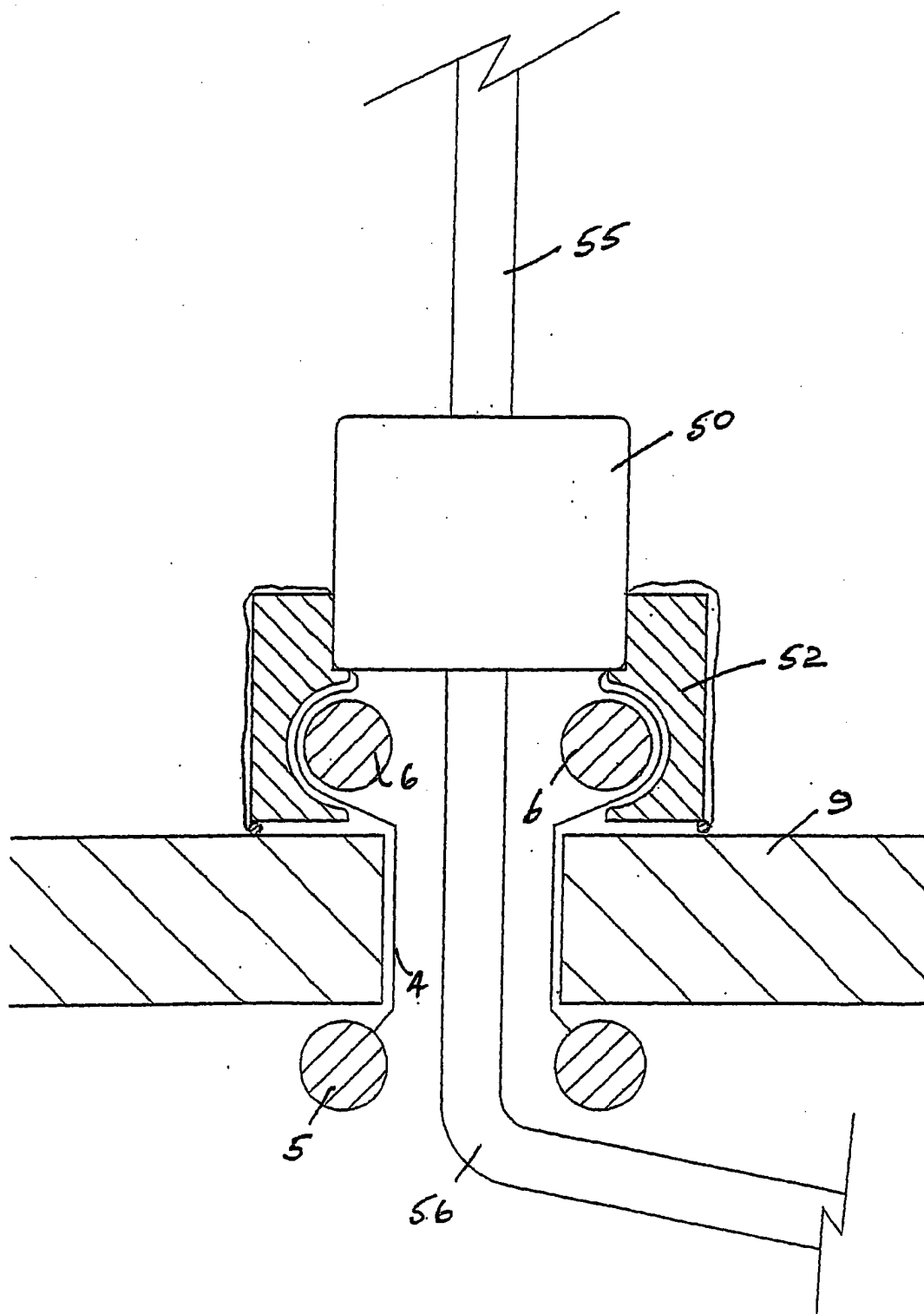


Fig. 26

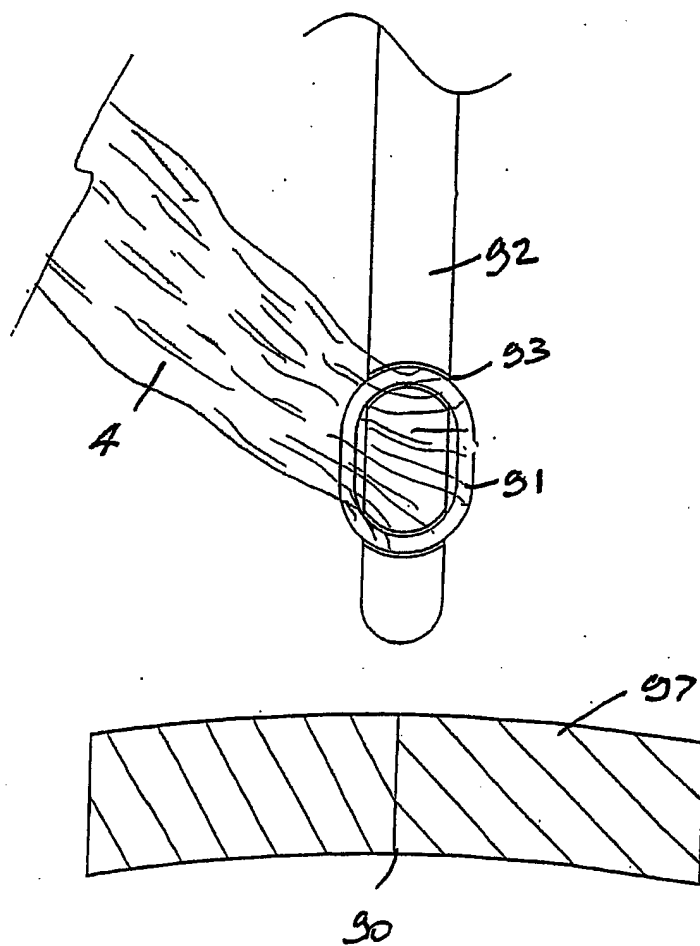


Fig. 27

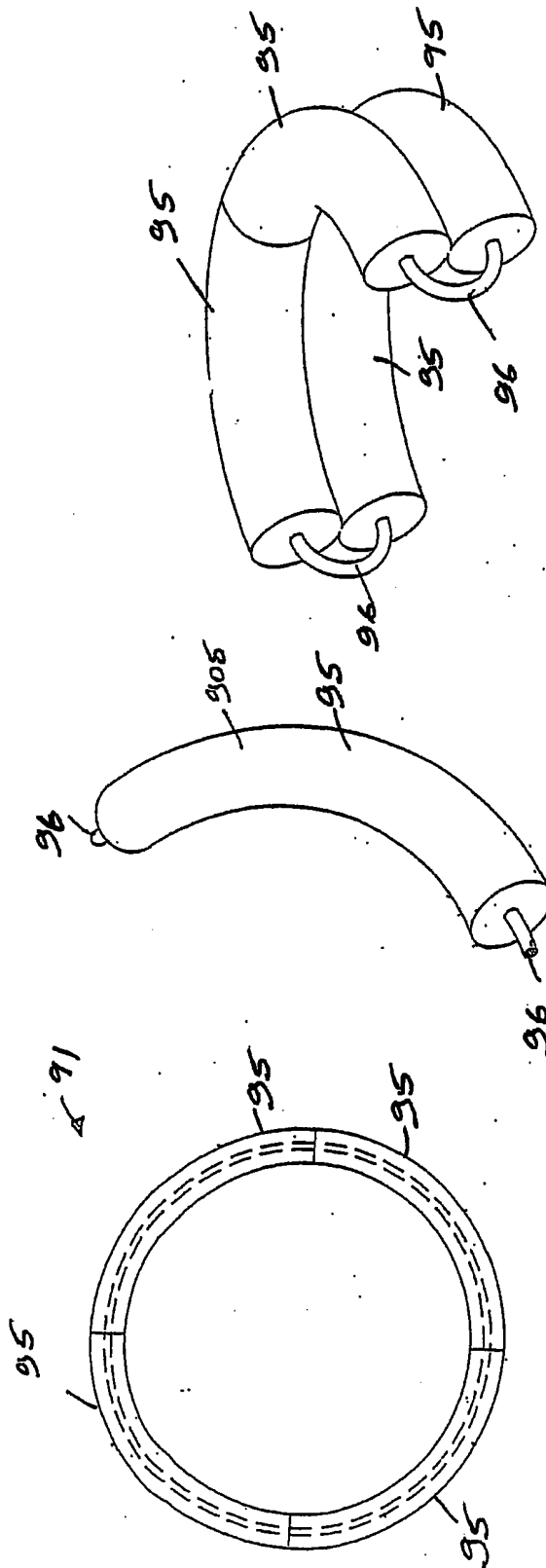


Fig. 28

Fig. 29

Fig. 30

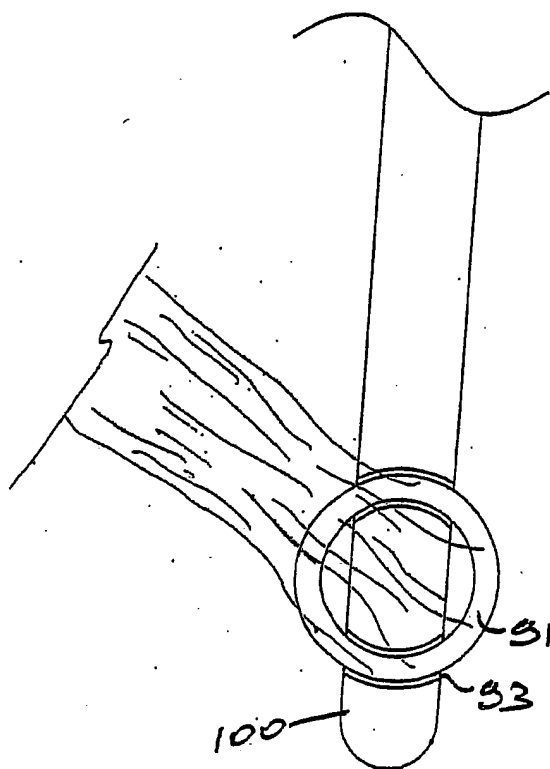


Fig. 31

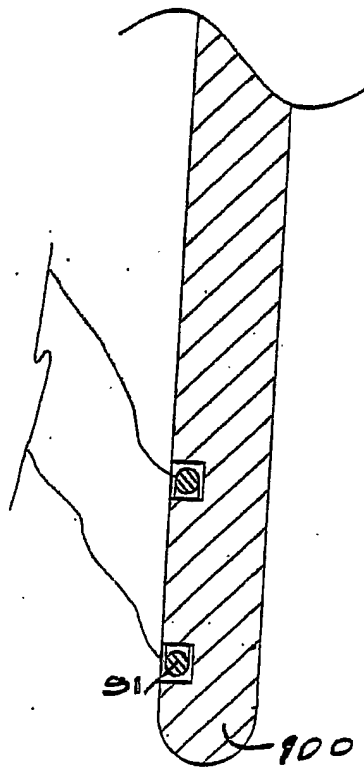


Fig. 32

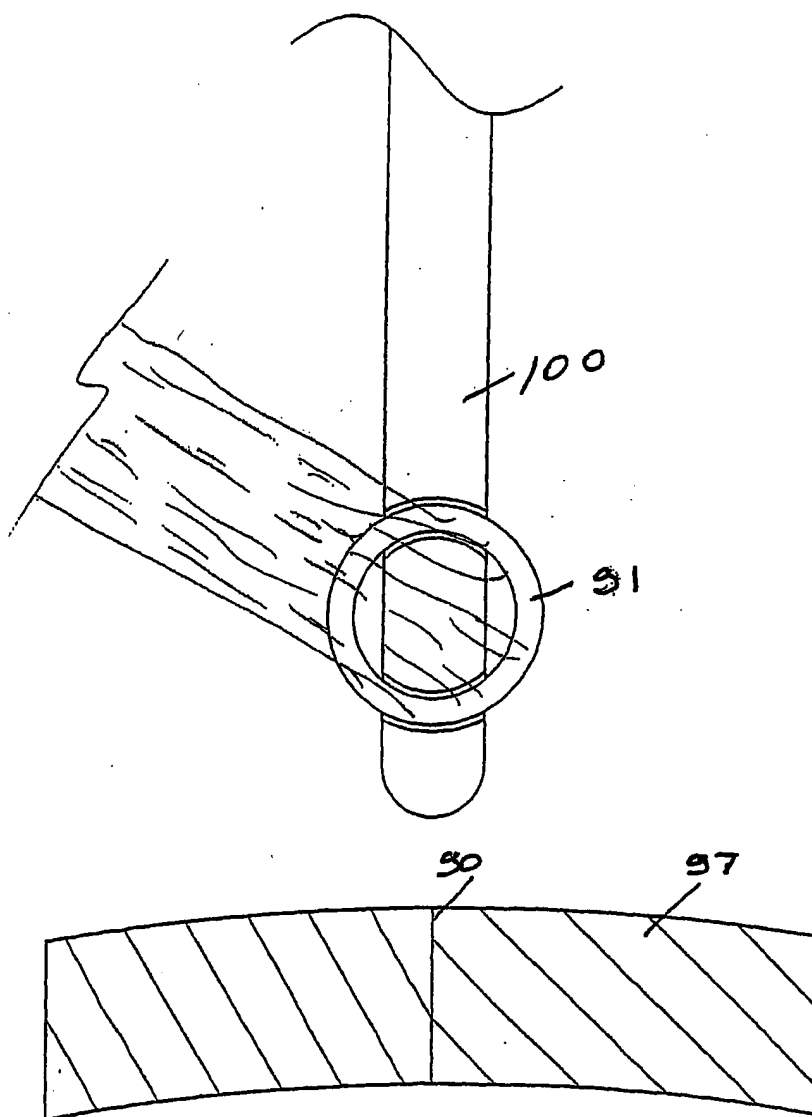


Fig. 33

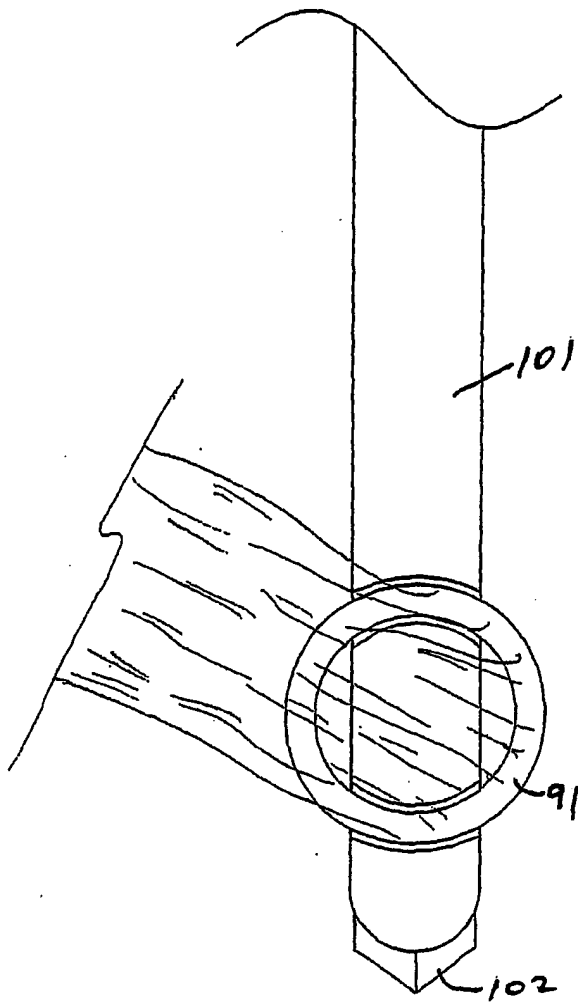


Fig. 34

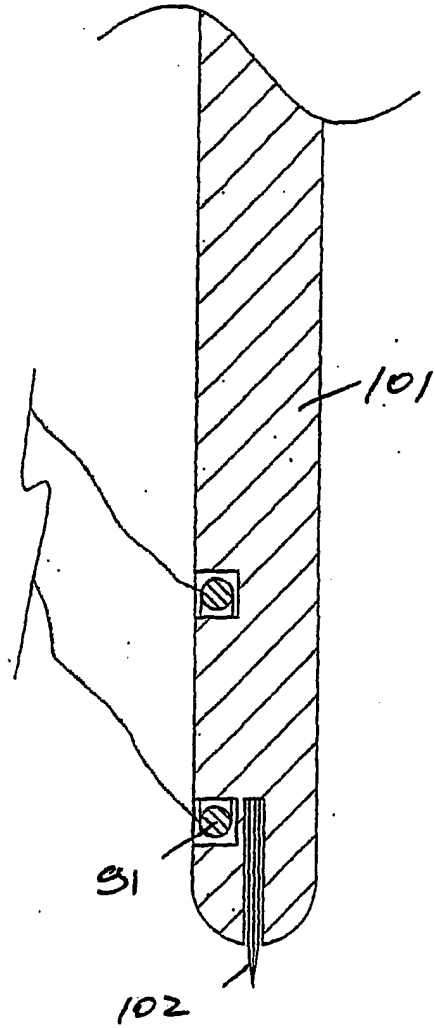


Fig. 35

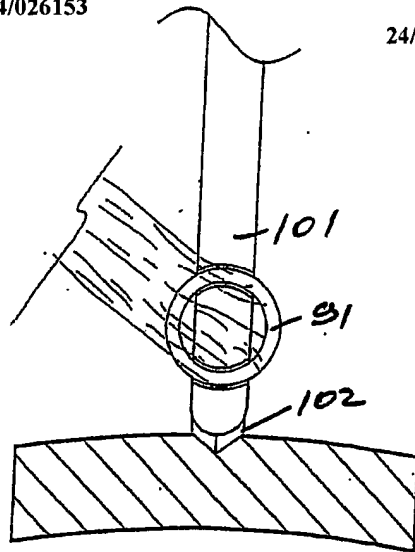


Fig. 36

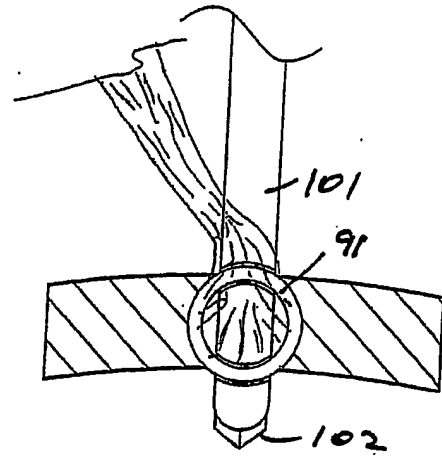


Fig. 37

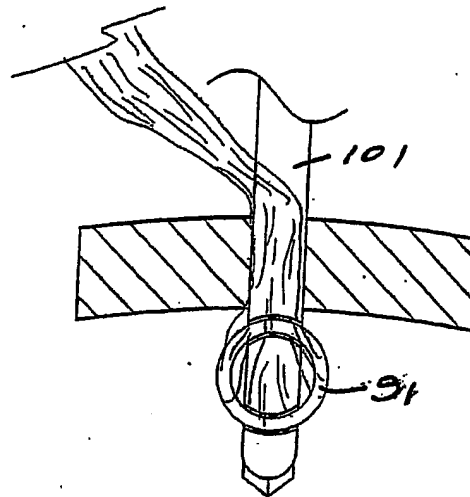


Fig. 38

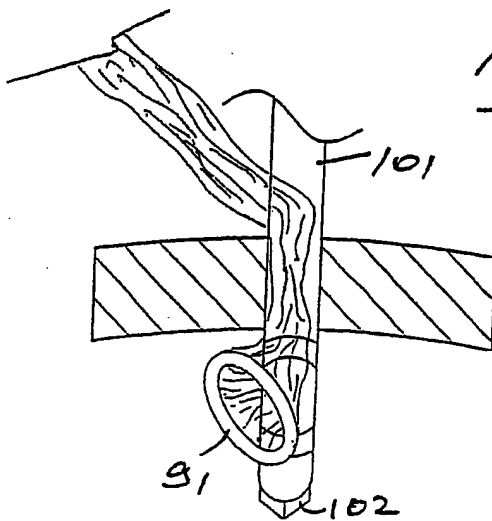


Fig. 39

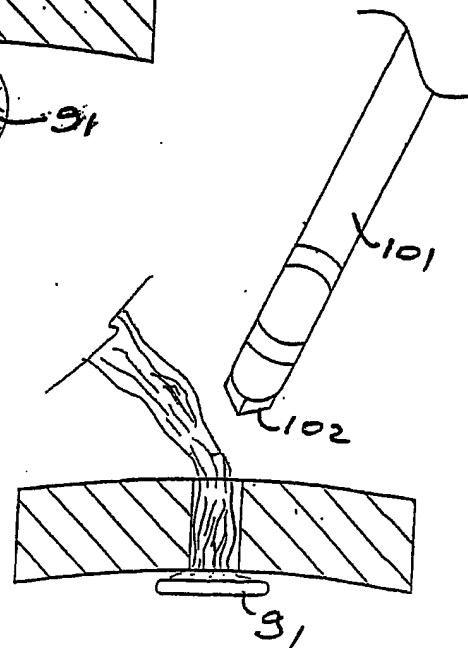


Fig. 40

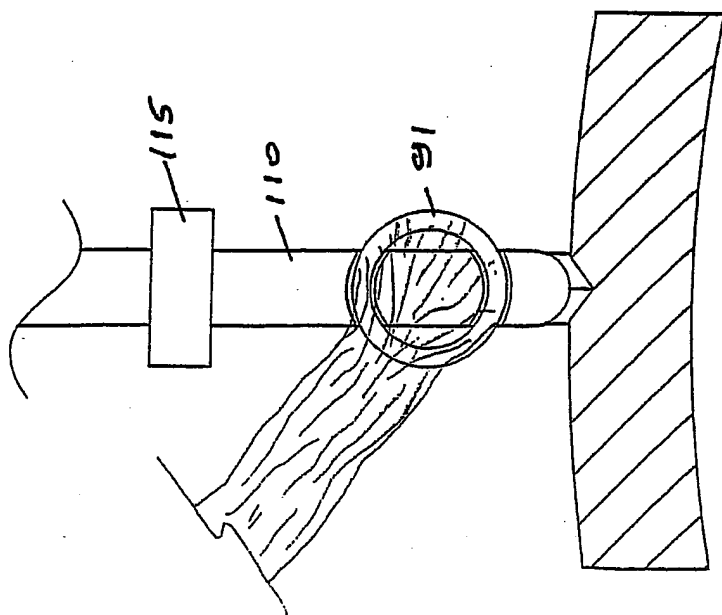


Fig. 41

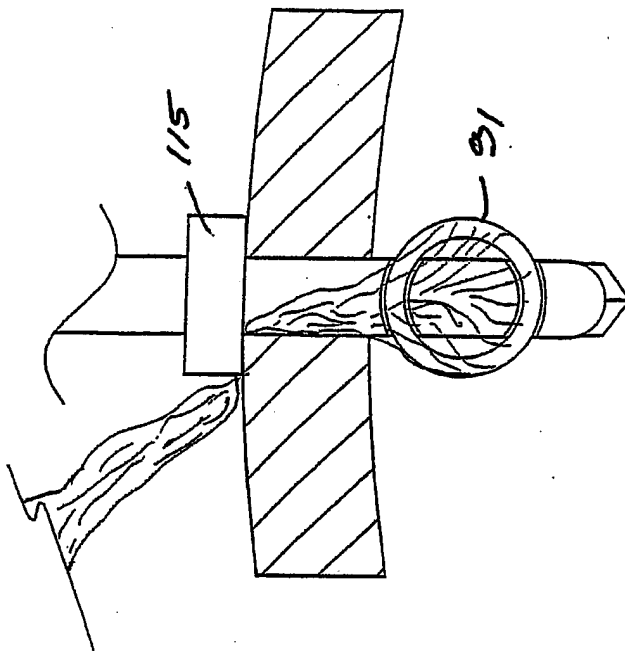


Fig. 42

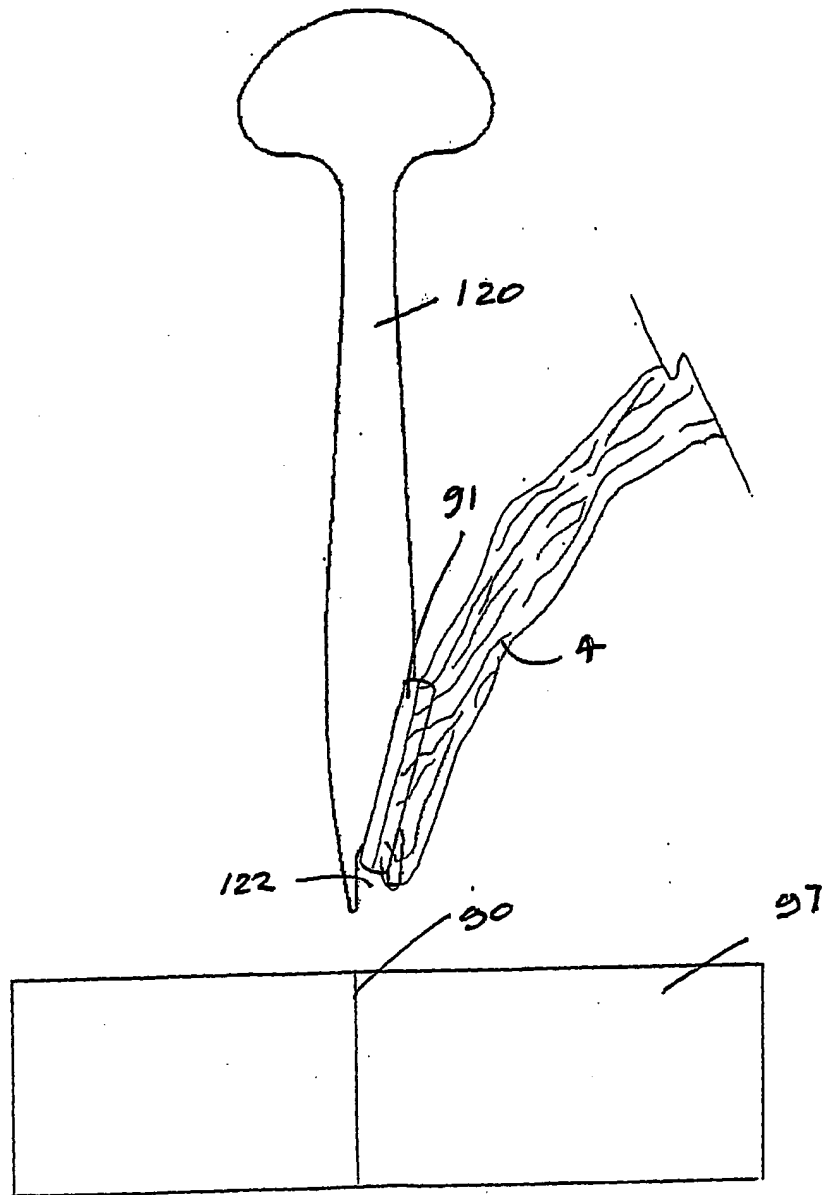


Fig. 43

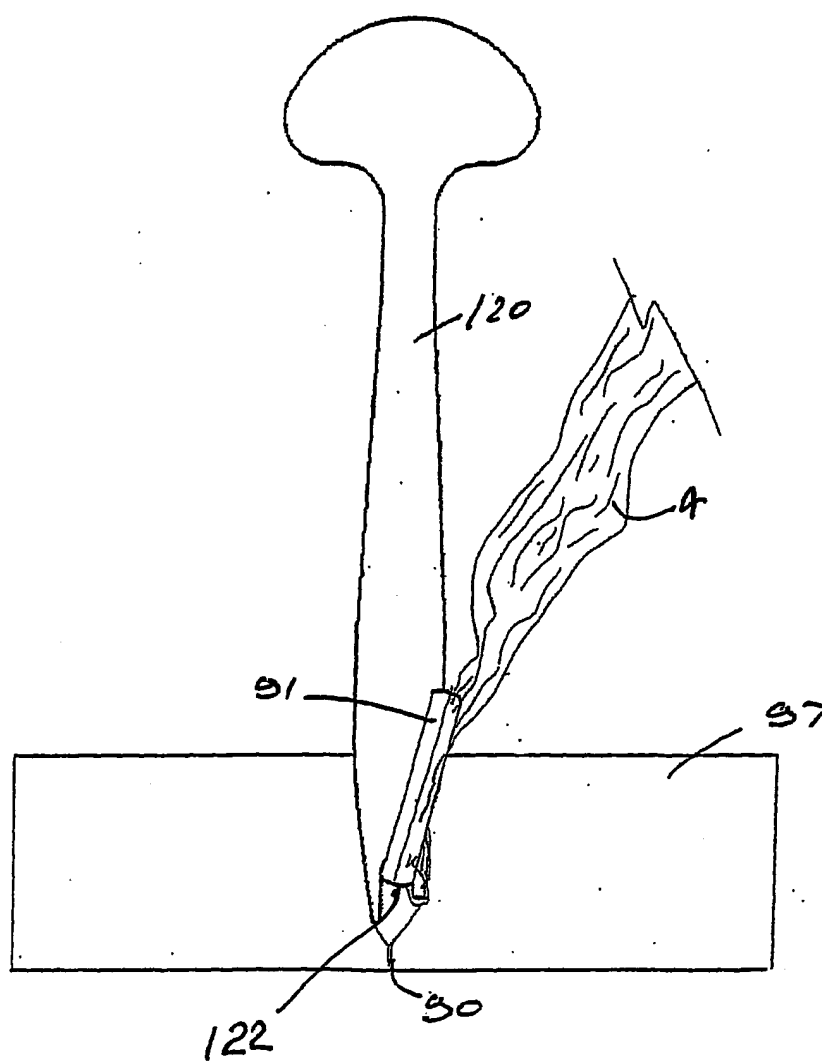


Fig. 44

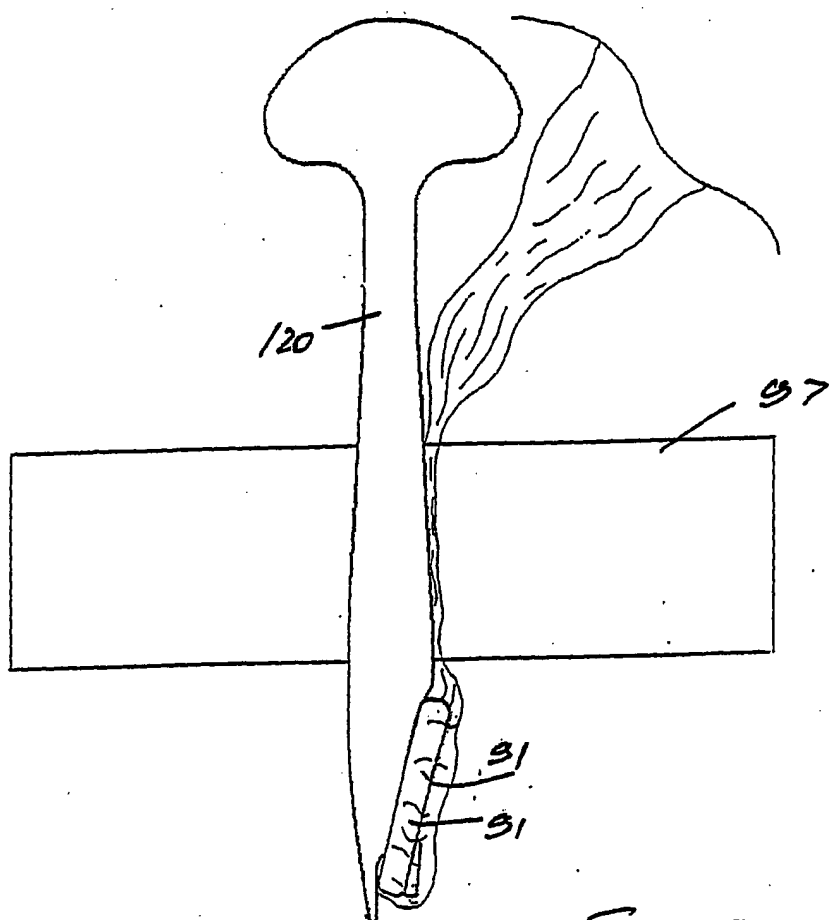


Fig. 45

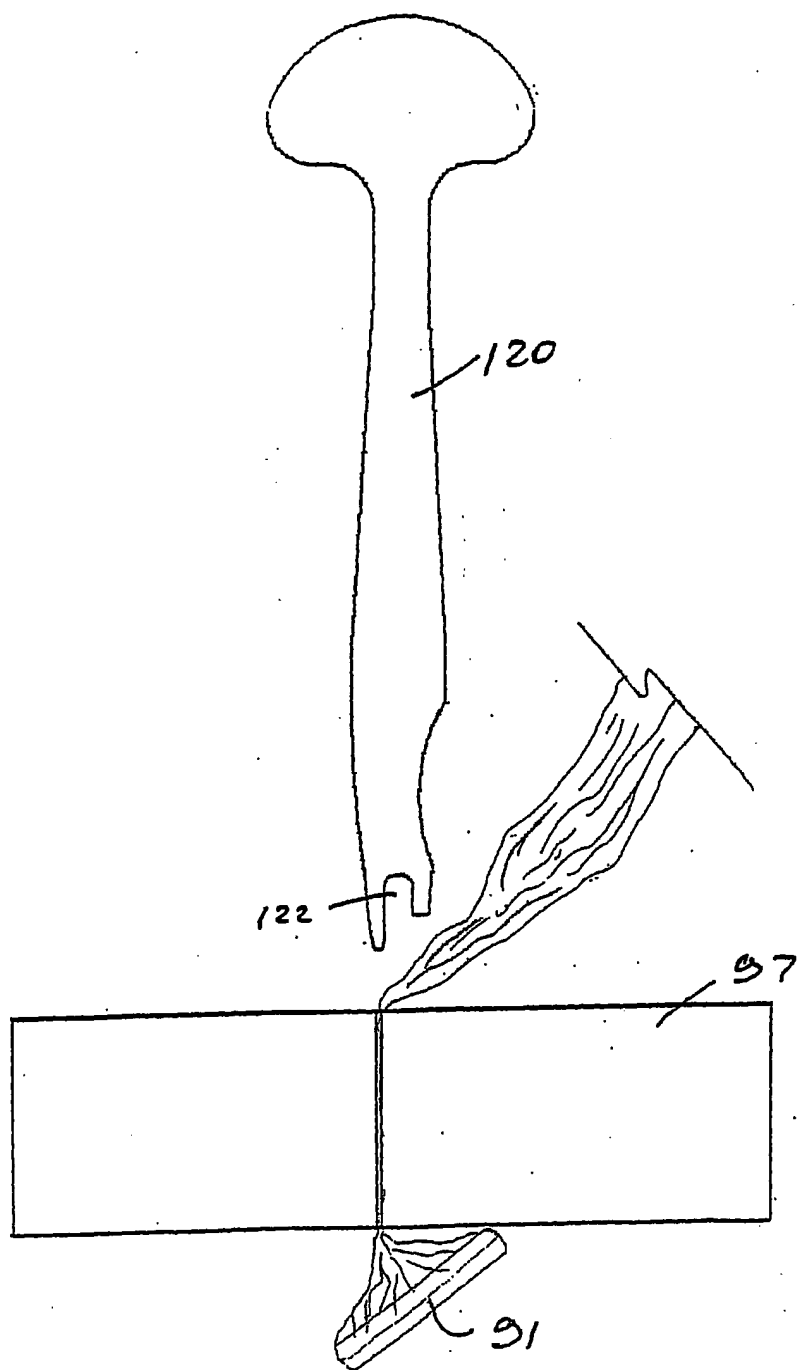


Fig. 46

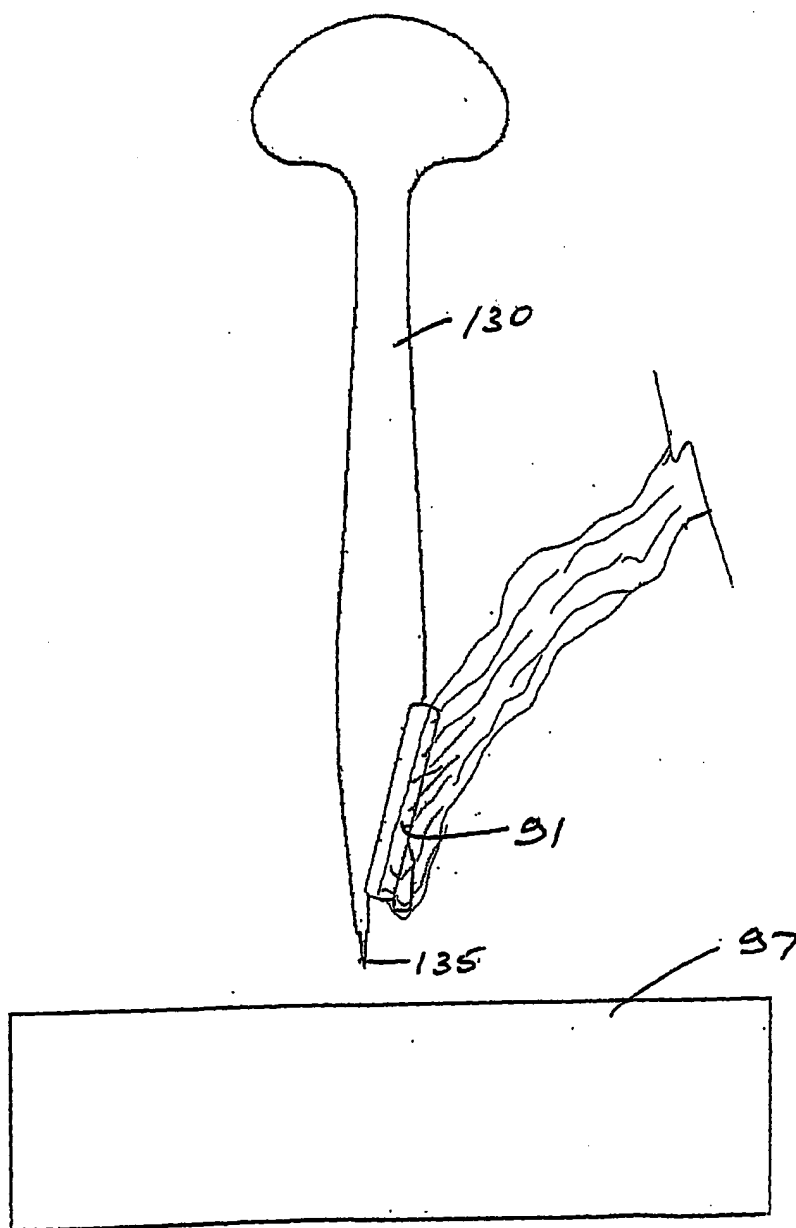


Fig. 47

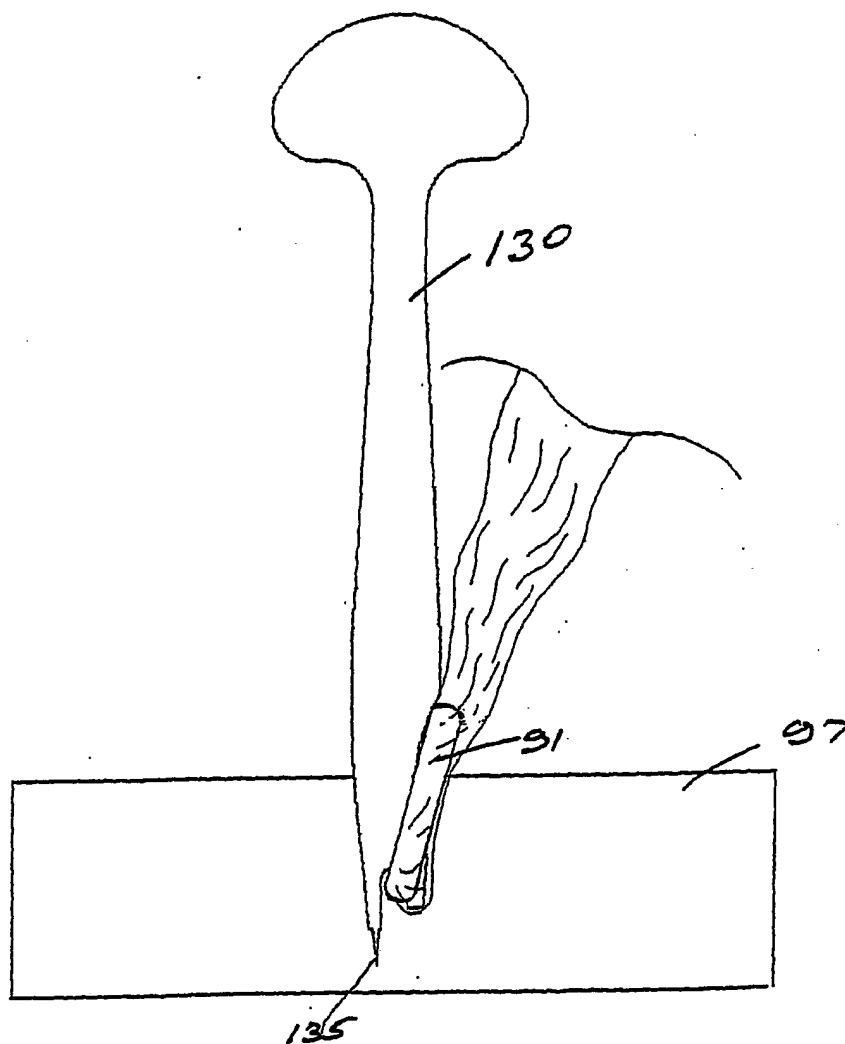


Fig. 48

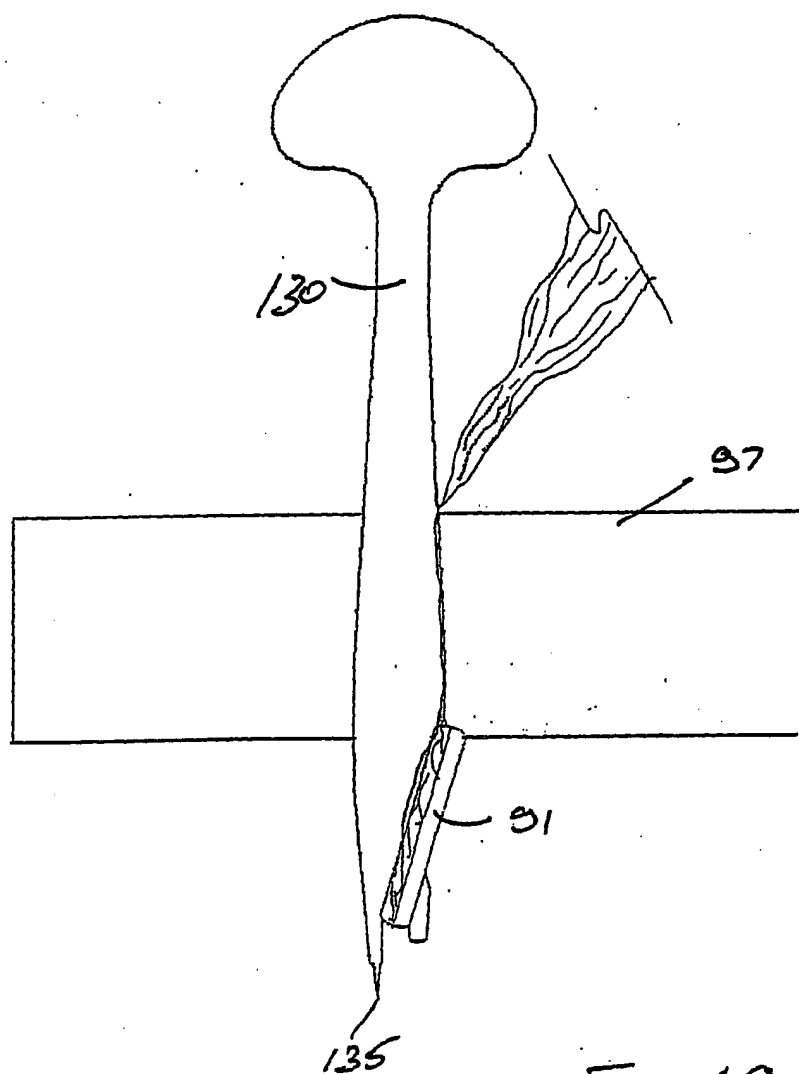


Fig. 49

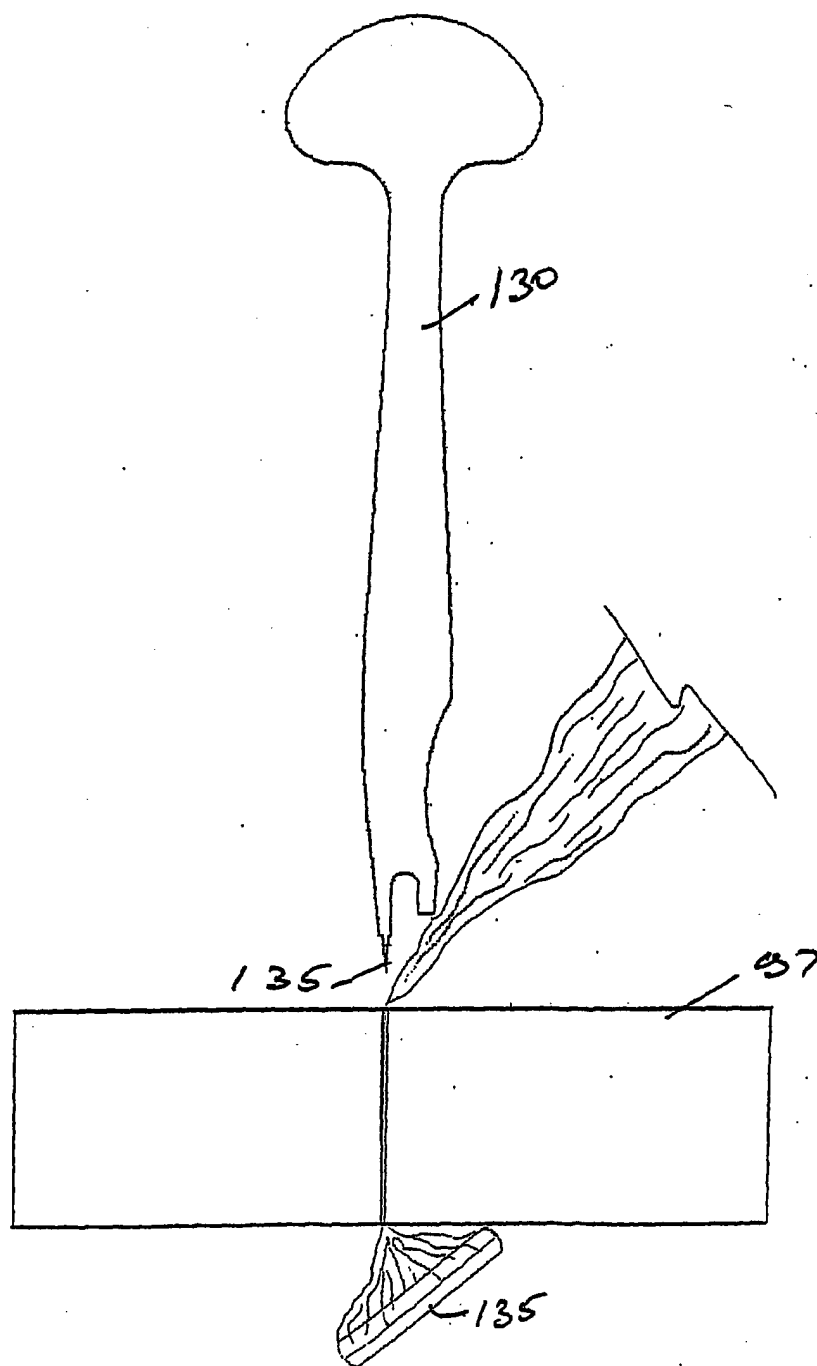


Fig. 50

INTERNATIONAL SEARCH REPORT

Inter Application No
PC 1 / 1 E 03/00126

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34 A61B17/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 171 282 B1 (RAGSDALE EDGAR K) 9 January 2001 (2001-01-09) column 2, line 40 - line 53; figure 1 column 3, line 21 - line 40; figures 2-5	1-9, 14, 38
Y	---	15-23, 26-29
X	WO 01 91652 A (YOUNG DEREK WILLIAM ;ATROPOS LTD (IE); BONADIO FRANK (IE); BUTLER) 6 December 2001 (2001-12-06) page 24, line 5 -page 25, line 2; figures 17-21	1, 8, 14, 38
X	US 5 391 156 A (NAGAO REX ET AL) 21 February 1995 (1995-02-21) figures 4-7	1, 8, 14, 38

	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

5 December 2003

Date of mailing of the international search report

17/12/2003

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Ducureau, F

INTERNATIONAL SEARCH REPORT

Intern Application No
PCT/IL 03/00126

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 254 534 B1 (YOUNG DEREK WILLIAM ET AL) 3 July 2001 (2001-07-03) column 4, line 8 - line 56; figures 1-3	17-23, 26-29
A	---	1
Y	US 6 382 211 B1 (CROOK BERWYN M) 7 May 2002 (2002-05-07) column 6, line 50 - line 66 figures 8A,8B	15,16
A	---	1,17,38
A	US 6 319 246 B1 (DE LA TORRE ROGER A ET AL) 20 November 2001 (2001-11-20) figures 7,8,25 -----	1,17, 31-37

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IE 03/00126

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 39-54
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Inter Application No
PCT/IE 03/00126

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6171282	B1	09-01-2001	NONE
WO 0191652	A	06-12-2001	AU 6418401 A 11-12-2001 WO 0191652 A1 06-12-2001 IE 20010519 A1 05-03-2003
US 5391156	A	21-02-1995	AT 185958 T 15-11-1999 AU 4136193 A 06-01-1994 CA 2099354 A1 31-12-1993 DE 69326860 D1 02-12-1999 DE 69326860 T2 20-04-2000 EP 0577400 A1 05-01-1994 ES 2139628 T3 16-02-2000 GR 93100244 A 28-02-1994 JP 7275252 A 24-10-1995 US 5490843 A 13-02-1996 US 5830191 A 03-11-1998 US 5562677 A 08-10-1996
US 6254534	B1	03-07-2001	EP 1125552 A1 22-08-2001 AU 7813100 A 23-04-2001 AU 7813200 A 23-04-2001 BR 0014683 A 11-06-2002 CA 2385835 A1 19-04-2001 CN 1378436 T 06-11-2002 WO 0126558 A1 19-04-2001 WO 0126559 A1 19-04-2001 IE 20000833 A1 06-02-2002 IE 20000835 A1 06-02-2002 JP 2003511145 T 25-03-2003 US 2002010389 A1 24-01-2002 ZA 200202174 A 10-10-2002
US 6382211	B1	07-05-2002	US 2002162559 A1 07-11-2002 AU 3888897 A 10-02-1999 EP 0999799 A1 17-05-2000
US 6319246	B1	20-11-2001	US 6024736 A 15-02-2000 US 5653705 A 05-08-1997 US 2002038077 A1 28-03-2002 WO 9610963 A1 18-04-1996 US 5672168 A 30-09-1997 US 5957913 A 28-09-1999